

Exhibit B

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF
3 WEST VIRGINIA AT CHARLESTON

- - -

4 IN RE: ETHICON, INC., : Master File No.
5 PELVIC REPAIR SYSTEM : 2:12-MD-02327
6 PRODUCTS LIABILITY : MDL 2327
7 LITIGATION :

8 -----
9 THIS DOCUMENT RELATES TO CASE
10 CONSOLIDATION:

11 Terreski Mullins, et al., v. Ethicon,
12 Inc., et al.

13 Case No. 2:12-CV-02952

- - -

14 September 17, 2015

- - -

15 Oral deposition of ANNE
16 HOLLAND WILSON, MBA, held in the offices
17 of Riker Danzig, 500 Fifth Avenue, New
18 York, New York 10110, commencing at
19 9:20 a.m., on the above date, before
20 Margaret Peoples, a Registered
21 Professional Reporter and Notary Public
22 in and for the States of Pennsylvania,
23 New York and Connecticut.

- - -

24 GOLKOW TECHNOLOGIES, INC.
 877.370.3377 ph|917.591.5672 fax
 deps@golkow.com

1 A P P E A R A N C E S :
2 WEXLER WALLACE, LLP
3 BY: EDWARD A. WALLACE, ESQUIRE
4 55 W. Monroe Street
5 Suite 3300
6 Chicago, Illinois 60603
7 (312) 589-6272
8 eaw@wexlerwallace.com
9 Counsel for the Plaintiffs
10 THOMAS, COMBS & SPANN, PLLC
11 BY: PHILIP J. COMBS, ESQUIRE
12 300 Summers Street
13 Suite 1380
14 Charleston, West Virginia 25301
15 (304) 414-1800
16 Pcombs@tcspllc.com
17 Counsel for the Defendants
18 BUTLER SNOW, LLP
19 BY: PAUL N. DAVIS, ESQUIRE
20 1020 Highland Colony Parkway
21 Suite 1400
22 Ridgeland, Mississippi 39157
23 (601) 948-5711
24 paul.davis@butlersnow.com
 Counsel for the Defendants

- - -

- - -
I N D E X

WITNESS PAGE NO.

ANNE HOLLAND WILSON, MBA

By Mr. Combs 9, 425

By Mr. Wallace 387, 436

- - -
E X H I B I T S

NO. DESCRIPTION PAGE NO.

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Rule 26 Expert Report of
Anne Wilson, MBA 29

Wilson 2

Total Hours July 26 -
September 14, 2015 30

Wilson 3

Report of Elaine Duncan,
MSME, RAC 30

Wilson 4

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21 CFR 820.1 71

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Medical Devices - Application
of risk management to
medical devices
Amendment 1: Rationale for
Requirements 102

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DEPOSITION SUPPORT INDEX

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Direction to Witness Not To Answer

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None

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Stipulations

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None

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16

Questions Marked

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None

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- - -

2

ANNE HOLLAND WILSON, after

3

having been duly sworn, was

4

examined and testified as

5

follows:

6

- - -

7

EXAMINATION

8

- - -

9

BY MR. COMBS:

10

Q. Could you state your name

11

for the record.

12

A. Anne Holland Wilson.

13

Q. Ms. Wilson, what's your

14

business address?

15

A. 7500 Rialto Boulevard,

16

Austin, Texas.

17

Q. How many times have you been

18

deposed before?

19

A. Once.

20

Q. Prior to the deposition, did

21

Mr. Wallace explain to you the ground

22

rules of the deposition, and that I don't

23

need to go back over those?

24

MR. WALLACE: I'll object

1 just to the extent that it calls
2 for privileged communications.

3 But assuming there's no
4 waiver, you can generally sort of
5 speak to that.

6 THE WITNESS: Why don't you
7 just go over any ground rules.

8 BY MR. COMBS:

9 Q. Obviously, the most
10 important thing is you're under oath, so
11 you have to tell the truth.

12 If I ask you any questions
13 and you don't understand them, let me
14 know.

15 If I ask you a question and
16 you don't understand it, let us know
17 immediately at that time, if you can.

18 If you have to discuss
19 something with Mr. Wallace, I'm not going
20 to object and throw a fit about it or
21 anything like that, but I would ask that
22 you answer the question that's pending
23 before you do that.

24 Today is not an endurance

1 contest, but we want to respect, you
2 know, convenience for you. If there's
3 any time today that you need to take a
4 break, just tell us.

5 Before the deposition,
6 Mr. Wallace and I talked, and he
7 indicated you would want to take some
8 breaks throughout. That's obviously fine
9 with us.

10 And as we get closer to
11 lunch, you can let us know if you want us
12 to order something in or just take a
13 break then.

14 A. Okay.

15 Q. But, you know, I don't think
16 there's any more magic than that.

17 A. Okay.

18 Q. Ms. Wilson, we got a copy of
19 your report, and attached to that report
20 is a copy of your CV.

21 A. Mm-hmm.

22 Q. Is that CV up to date?

23 A. Yes.

24 Q. And does it have all the

1 publications that you have authored?

2 A. Yes.

3 Q. No publications that would
4 postdate that version of the CV?

5 A. No.

6 Q. You said that you had
7 testified one time before. Was that as a
8 fact witness or an expert witness?

9 A. It was an expert.

10 Q. And is that one of the cases
11 that's listed on your reliance list?

12 A. Yes.

13 Q. Which one of the cases is
14 that?

15 A. There was only one listed.
16 It was Parcus, and...

17 Q. Okay. Well, you also had
18 the BMD versus Medtronic?

19 A. Right, but that wasn't a
20 deposition.

21 Q. Okay. You got the BMD
22 versus Medtronic. And was that a case --

23 THE WITNESS: Can I turn
24 that off?

1 MR. COMBS: Of course.

2 BY MR. COMBS:

3 Q. All right. On your CV,
4 you've got listed, Expert Witness in
5 Litigation Support, and you've got four
6 things listed there.

7 So the first one, BMD versus
8 Medtronic, is that a case in which you
9 just prepared a report?

10 A. Yes.

11 Q. And you have not testified
12 yet?

13 A. That was -- I have to look,
14 but that was like ten years ago.

15 Q. Oh, okay. I saw 2005, I
16 thought it said 2015.

17 What was that case?

18 A. That was a case relating to
19 if due diligence was done properly in a
20 designed -- implantable device design.

21 Q. What was the device?

22 A. It was a tissue valve.

23 Q. And what type of tissue
24 valve?

1 A. Porcine.

2 Q. Were you testifying on
3 behalf of the plaintiff or defendant?

4 A. Defense. Well, you know, I
5 was testifying on behalf of Medtronic,
6 so...

7 Q. The Parcus case, that's the
8 case in which you gave a deposition?

9 A. Yes.

10 Q. And what was that case
11 about?

12 A. That was about
13 confidentiality of quality management
14 systems.

15 Q. And --

16 A. And proprietary, are they
17 proprietary or not.

18 Q. And who were you testifying
19 on behalf of in that case?

20 A. Parcus.

21 Q. Did that case go to trial?

22 A. It did not.

23 Q. Who was the lawyer that you
24 were working with in the Medtronic case?

1 A. I'm sorry. I can't recall.
2 That was -- they were in Minnesota. I
3 can tell you that.

4 Q. And who was the lawyer that
5 you were working with in the Parcus
6 Medical case?

7 A. I would have to look it up.

8 Q. You don't remember?

9 A. I don't remember his name.
10 I know exactly what he looks like.

11 Q. Where did that lawyer
12 practice?

13 A. In Boston.

14 Q. You've also got two
15 references to litigation support?

16 A. Correct.

17 Q. What does that mean?

18 A. I'm doing some background
19 support work, helping write protocols and
20 evaluate information analyses.

21 Q. And so let me ask you first
22 about the work with Sanford Heisler.

23 Where is Sanford Heisler?

24 A. In New York.

1 Q. And what -- broadly
2 speaking, what did you do for Sanford
3 Heisler?

4 A. Basically, gave some advice
5 about implantable devices and...

6 Q. What type of implantable
7 devices?

8 A. Hips.

9 Q. And was that in connection
10 with any of the hip implant litigation?

11 A. Yes.

12 Q. And have you prepared any
13 reports --

14 A. No.

15 Q. -- for that?

16 A. Just sporadic advice here
17 and there.

18 Q. So if I could paraphrase
19 that.

20 So lawyers call you when
21 they have issues that relate to your
22 field of expertise and ask you questions
23 about it?

24 A. Exactly.

1 Q. How often are you working on
2 that?

3 A. Rarely.

4 Q. This is the specificity I
5 need. Is it once a week, once a month,
6 once a year?

7 MR. WALLACE: If you know.

8 THE WITNESS: Twice a year.

9 BY MR. COMBS:

10 Q. Grant Morris, what does that
11 assignment entail?

12 A. That's actually doing some
13 development of a test protocol, some
14 research.

15 Q. And what is the product at
16 issue that will be tested?

17 A. It's various products,
18 various implantable devices.

19 Q. What implantable devices,
20 what classes?

21 A. There's total joints and
22 spine instruments, various materials.
23 Not cardiovascular.

24 Q. I apologize. I thought you

1 said it was total joints?

2 A. Total joints. Knees, hips,
3 shoulders.

4 Q. Sure. So not anything
5 related to stress urinary incontinence?

6 A. No.

7 Q. Not anything related to
8 pelvic floor?

9 A. No.

10 Q. Ms. Wilson, of the nine
11 publications that are on your CV, how
12 many of those have been peer-reviewed?

13 A. One.

14 Q. Is that the one from
15 approximately 1986?

16 A. Probably, yes.

17 Q. Okay.

18 A. Yes, it is.

19 Q. It's --

20 A. Absolutely. That's
21 locomotive.

22 Q. "Automated Extraction,"
23 blah, blah, blah.

24 A. Yes, that's it.

1 Q. You're not relying on that
2 for any part of your testimony today, are
3 you?

4 A. No, sir.

5 Q. I saw that you had a
6 publication called, "Risk Management
7 Methods for Medical Devices" from 2001.

8 How do I get a copy of that?

9 A. I probably have to go back
10 to my office and see if my office manager
11 could help with that.

12 Q. Do you have a copy of it?

13 A. I don't have one with me.

14 Q. I didn't mean with you, but
15 do you have access to a copy of it?

16 A. I'm sure we can dig through
17 and it would be somewhere.

18 Q. Okay. Could you provide --

19 A. I'm not sure. I believe
20 that we could dig up a copy somewhere.
21 That's been a long time.

22 Q. Okay. Here's what I would
23 ask. So I would ask that you make
24 efforts to find a copy of that and that

1 you provide that to Mr. Wallace.

2 MR. WALLACE: Can you do me
3 a favor and send me something?

4 MR. COMBS: Sure.

5 MR. WALLACE: Otherwise,
6 it's going to get lost in the
7 shuffle of the deposition.

8 MR. COMBS: Yes.

9 BY MR. COMBS:

10 Q. Ms. Wilson, none of the
11 publications that are listed on your
12 curriculum vitae involve surgical mesh,
13 do they?

14 A. No.

15 Q. And you've never published
16 on Prolene mesh, have you?

17 A. No.

18 Q. You've never published on
19 the TVT product?

20 A. No.

21 Q. Never published on stress
22 urinary incontinence?

23 A. No.

24 Q. Never published anything

1 regarding any of the risks that are
2 associated with stress urinary
3 incontinence devices?

4 A. I have not.

5 Q. I ask you about the
6 publications on your list.

7 Are there any additional
8 presentations that haven't made it to
9 your CV yet?

10 A. I need to take a look.
11 I believe that's complete.

12 Q. Ms. Wilson, I forget the
13 exact year, I think maybe it was 2000,
14 but is that when you left Sulzer?

15 A. I worked for Carbomedics,
16 and that was in 1999.

17 Q. And is Carbomedics a
18 division of Sulzer?

19 A. It had several owners. So
20 at one time it was part of Sulzer.

21 Q. What did Carbomedics make?

22 A. Heart valves.

23 Q. Did Carbomedics have
24 anything to do with set Sulzer's

1 artificial hips?

2 A. No.

3 Q. And did you --

4 A. Could you ask me that again.

5 Q. Did Carbomedics have
6 anything to do with the artificial hips
7 marketed by Sulzer?

8 A. No.

9 Q. Did you ever work on any of
10 the artificial hip products that were
11 manufactured and sold by Sulzer?

12 A. No.

13 Q. Did you ever work on any of
14 the quality systems that were used in
15 relation to the hips sold by Sulzer?

16 A. There may have been some
17 shared quality systems. I'm not aware of
18 that, because I didn't work on the hips.
19 But given they had the same parent
20 company, there could have been, and I'm
21 just not aware.

22 Q. What types of quality
23 systems could have been shared between
24 Carbomedics and Sulzer's hip division?

1 A. There could have been
2 high-level policies.

3 Q. And what would those
4 policies encompass?

5 A. It could be quality manuals,
6 there could be statements.

7 Q. Risk management, standard
8 operating procedures?

9 A. No. Those were at the
10 division level.

11 Q. After you left Sulzer, it's
12 my understanding, from look at your CV,
13 that you have worked as a consultant.

14 Is that how you describe it?

15 A. Yes.

16 Q. Approximately how many
17 companies have you consulted with since
18 you left?

19 A. That's tricky. I'd have to
20 count. Fifty.

21 Q. I was going to ask you --

22 A. Fifty to 100, I would say.

23 Q. I was going to ask you, more
24 or less than 20. So 50 to 100 is fine.

1 Now, you say in your CV that
2 you have worked with implantables.

3 What does that mean to you?

4 A. Any device that's
5 permanently implanted.

6 Q. What types of permanently
7 implanted devices have you worked for?

8 A. I have worked in
9 cardiovascular, obviously, in heart
10 valves and annuloplasty rings. I've
11 worked in -- oh, sorry spine devices. I
12 have worked in suture anchors. Six
13 different kinds of spine devices.

14 Total joints: Hips, knees,
15 shoulders.

16 So I think that I worked for
17 at least 13 different types of
18 implantable devices.

19 Q. Have any of these involved
20 mesh?

21 A. No.

22 Q. Have any of them involved
23 hernia products?

24 A. I did work for a large

1 animal facility that had a study that
2 involved mesh. They were not my -- I
3 mean, mesh was not my client. The
4 animals facility was my client.

5 Q. Was this a facility that was
6 studying a mesh for hernia applications?

7 A. Yes.

8 Q. Did you have any involvement
9 with that project?

10 A. I was the QA unit, because
11 I'm registered in good laboratory
12 practices.

13 Q. Do you remember what type of
14 mesh that was?

15 A. I don't. There were several
16 different types.

17 Q. Do you know what it was made
18 of?

19 A. I do not.

20 Q. Would you have had any
21 active role in designing the clinical
22 trial?

23 A. No.

24 Q. Have any of the implantables

1 that you have consulted on involved
2 products that treat stress urinary
3 incontinence?

4 A. No.

5 Q. Have any of the devices that
6 you have worked on involved pelvic floor
7 products?

8 A. No.

9 Q. And to the best of your
10 knowledge, none of them have involved
11 polypropylene or Prolene?

12 A. I'm just thinking. No.

13 Q. When were you first
14 contacted about this litigation?

15 A. What is it now, September?
16 Maybe July.

17 Q. And who contacted you?

18 A. Actually, I met with Brianne
19 [ph], but I can't remember her last name.
20 She got married, and I just can't
21 remember her last name.

22 Q. Was Brianne one of the
23 lawyers that is working with the group
24 that has retained you in this case?

1 A. Yes.

2 MR. COMBS: Ed, I don't know
3 Brianne. Do you know Brianne?

4 MR. WALLACE: (Gesturing.)

5 MR. COMBS: What's Brianne's
6 last name?

7 MR. WALLACE: No.

8 THE WITNESS: Exactly.

9 MR. COMBS: All right.
10 Never mind.

11 BY MR. COMBS:

12 Q. What were you asked to do in
13 the case?

14 A. At that point, nothing. We
15 just got back in touch and asked if I
16 would be interested in working on some
17 design control and risk
18 management-related work.

19 Q. And how many times have you
20 met with counsel regarding this project?

21 MR. WALLACE: Do you mind if
22 I ask in person?

23 MR. COMBS: Sure.

24 BY MR. COMBS:

1 Q. We'll start with how many
2 times in person.

3 More or less than five?

4 A. Twice in DC -- less than
5 five.

6 Q. And approximately, how many
7 hours have you spent?

8 A. With counsel or in total?

9 Q. Yes. With counsel.

10 A. Can we look at the details
11 on that?

12 Q. Sure.

13 A. I don't have it memorized.

14 Q. Okay. Did you bring --

15 MR. WALLACE: Do you mind if
16 I make a quick statement?

17 MR. COMBS: Sure.

18 MR. WALLACE: So we are
19 providing you with a -- it's
20 called total hours, and it was
21 prepared in connection with this
22 deposition so that you could have
23 a record of the hours.

24 Obviously, she can speak to

1 this.

2 And while I'm at it -- and
3 I'd like to go ahead and have that
4 marked, if you don't mind.

5 While I'm at it, there are a
6 number of documents that are in
7 front of you, including binders
8 and a book and her report and
9 Ms. Duncan's report.

10 I don't know what you're
11 going to do with it, but I wanted
12 to note that all of this
13 information is being provided to
14 you pursuant to your Notice of
15 Deposition, and our objections to
16 your Notice of Deposition.

17 So with that, I'll turn it
18 back over to you.

19 MR. COMBS: Okay. Thanks.

20 Let's go ahead and mark --
21 we'll mark your copy of the report
22 as Exhibit 1.

23 - - -

24 (Whereupon, Exhibit Wilson 1

1 was marked for identification.)

2 - - -

3 MR. COMBS: So, for the
4 record, we've marked your copy of
5 the report as Exhibit 1.

6 - - -

7 (Whereupon, Exhibit Wilson 2
8 was marked for identification.)

9 - - -

10 MR. COMBS: So for the
11 record we've marked what
12 Mr. Wallace handed us that's
13 entitled "Total Hours" as
14 Exhibit 2.

15 And then we'll mark as
16 Exhibit 3 Ms. Wilson's copy of
17 Elaine Duncan's report.

18 - - -

19 (Whereupon, Exhibit Wilson 3
20 was marked for identification.)

21 - - -

22 BY MR. COMBS:

23 Q. Ms. Wilson, on Exhibits 1,
24 which is your copy of your own report,

1 and Exhibit 3, which is your copy of
2 Ms. Duncan's report, there are a number
3 of handwritten notations.

4 Did you make all those?

5 A. I sure did.

6 Q. Okay. So anything that's on
7 here was something by you.

8 A. Yes.

9 Q. Wouldn't have been written
10 by anybody else.

11 A. No.

12 Q. Thank you.

13 Ms. Wilson on Exhibit 2,
14 where you have got the total hours that
15 you spent on the project, would that be
16 the monies that you have billed to date
17 on the project?

18 A. Yes. Well, correction.

19 Q. Current to when?

20 A. This was actually through
21 September 14th, but we didn't bill for
22 September yet. So there's 14 days that
23 had not been billed yet.

24 Q. Approximately, how many

1 hours will be added by virtue of the fact
2 that you didn't have the period from
3 September 1st to September 14th billed?

4 A. I believe I spent about 30.

5 Q. So -- and, again, nobody is
6 going to hold you to that. Just
7 something in the neighborhood of 30 hours
8 between --

9 A. Yes.

10 Q. -- September 1st and
11 September 14 --

12 A. Correct.

13 Q. -- that would make the total
14 hours spent on the project something like
15 230 hours.

16 A. No. My hours between the
17 1st and the 14th have already been
18 included in here.

19 So that 198 includes those
20 hours. So it would not be additive.

21 Q. All right. Is the total
22 right or would the total change when you
23 issue the September bill?

24 A. We bill monthly. So the

1 September mid-month total is correct.

2 Could you clarify your
3 question?

4 Q. Yes. I guess I'm not doing
5 a very good job asking. Here's all I'm
6 trying to figure out.

7 You say that up to
8 September 14 you had worked 198 hours; is
9 that correct?

10 A. My group.

11 Q. And so far, you have billed
12 \$57,075.95.

13 A. That's not correct.

14 Q. Okay.

15 A. I haven't billed for the
16 first 14 days of September, but that
17 total includes those money.

18 Q. Thank you. So after you
19 issue that bill, this would be current as
20 of September 14?

21 A. We will never issue a bill
22 between the mid-month period. So this
23 will never be a total that comes out.
24 This was completed on for today's

1 purposes.

2 Q. So it will include this
3 amount --

4 A. Plus --

5 Q. -- plus whatever --

6 A. -- the other half --

7 Q. -- whatever you do between
8 now and the end of the month.

9 A. Correct.

10 Q. But as of September 14,
11 that's the amount that would have been
12 charged if a bill had been issued on that
13 date.

14 A. Correct.

15 Q. You say that it's work done
16 by your group.

17 Does that include the
18 quality associate and quality specialist?

19 A. Correct.

20 Q. You are the expert?

21 A. Yes.

22 Q. And is this all done through
23 your QA consulting business?

24 A. Yes.

1 Q. So the quality associate is
2 somebody that's retained in some capacity
3 by QA, and the quality specialist is
4 somebody that's retained in some capacity
5 by QA?

6 A. Yes.

7 Q. You told us that you have
8 met with the lawyers a few times,
9 something less than five times.

10 I assume that's also
11 included telephone conferences?

12 A. Yes.

13 Q. Approximately how many times
14 have you spoken to counsel on the phone?

15 A. Oh, boy. I only recall once
16 on the phone.

17 Q. Ms. Wilson, I'm going to ask
18 you more questions about this later in
19 the deposition, but you've got a reliance
20 list that's got the documents that you
21 reviewed.

22 Are those all of the
23 documents that you were relying on in
24 this case?

1 A. Those were the documents
2 that I had available to me.

3 Q. So the Exhibit 3 to your
4 report, that would be the universe of
5 documents that you had to review?

6 A. And I could ask for more.

7 Q. Okay.

8 A. I often ask for, Oh, how
9 about this, how about that. So...

10 Q. By the time the report was
11 done and the opinions were formed, this
12 was the universe of stuff that you had
13 been provided.

14 A. Yes.

15 Q. Ms. Wilson, were there any
16 documents which were provided that you
17 chose not to put on the reliance list?

18 A. Not to my knowledge.

19 Q. Have you spoken with any
20 other experts in this litigation?

21 A. No.

22 Q. So is it a fair statement
23 that there is nothing in your report that
24 you're predicating on the opinion of

1 another expert?

2 A. Correct.

3 Q. The opinions that you're
4 offering in this case, you've never
5 published any of them, have you?

6 A. No.

7 Q. You've never tested any of
8 them, have you?

9 A. I don't think I understand
10 what you mean by that question.

11 Q. Well, have you ever tested
12 any of these opinions?

13 A. I'm a consultant and I have
14 tested for 20 years or 30 years of
15 experience. I do this every day for a
16 living.

17 Q. So how is it that your
18 opinions in this case have been tested?

19 MR. WALLACE: Objection to
20 form.

21 THE WITNESS: I don't
22 understand what you mean by
23 "tested" then.

24 BY MR. COMBS:

1 Q. Has anyone else reviewed
2 these opinions?

3 A. These are my opinions. I
4 wrote them.

5 Q. Have they been reviewed by
6 anyone?

7 MR. WALLACE: Objection to
8 form.

9 THE WITNESS: I don't
10 understand who you're speaking
11 about.

12 BY MR. COMBS:

13 Q. Is there -- what is the
14 methodology that you used in order to
15 prepare that report?

16 A. I looked at many, many,
17 many, many, many documents and chose
18 those that best related to the topics of
19 risk management, assign control.

20 And then I took those
21 documents and reviewed them again, and
22 started writing. Did an outline. And I
23 kept refining and refining, and came up
24 with my report.

1 Q. I saw in your CV that you
2 hold yourself out as having expertise in
3 auditing.

4 Is that a fair statement?

5 A. Yes. I am certified in
6 auditing.

7 Q. Was, in essence, what you
8 were doing an audit --

9 A. No.

10 Q. -- of the design control?

11 A. Not at all.

12 Q. And why is it that you say
13 it is not?

14 A. Audits are very specific and
15 they're done in accordance with the
16 specific snapshot in time, a certain
17 location, certain standards. And they're
18 directly inquiring with a person, not
19 just relying on documents. So they're
20 not at all the same.

21 Q. So the methodology that you
22 used in preparation for this report would
23 not be the methodology that you would use
24 when conducting an audit?

1 A. No.

2 Q. It's not the same?

3 A. No. They're not the same.

4 Q. And so the methodology that
5 you use as an auditor is not something
6 that you're relying on in support of this
7 report.

8 A. I use my expertise and
9 knowledge as a consultant doing a variety
10 of things, and use all of them together
11 to assist me in evaluating the data and
12 writing the report.

13 Q. And the methodology that you
14 apply in an audit is not something that
15 you applied in the preparation of this
16 report?

17 MR. WALLACE: Objection to
18 form. Asked and answered.

19 THE WITNESS: Could you ask
20 me this again.

21 BY MR. COMBS:

22 Q. Yeah.

23 A. I think I answered that one
24 already.

1 Q. Okay. Well, I just want to
2 make sure that I understand.

3 I mean, it's my
4 understanding that the process by which
5 you do an audit would be very different
6 than the process by which you prepared
7 this report and the opinions contained in
8 this report.

9 Is that correct?

10 MR. WALLACE: Objection to
11 form.

12 THE WITNESS: Audits use one
13 set of skills. Expert report uses
14 some of those skills, but they're
15 not all the same.

16 I used the sum of my
17 knowledge as a consultant in risk
18 management, auditing, GLPs, design
19 controls, 15 years of work
20 experience, 15 years of business
21 ownership, consultants to come up
22 with my report.

23 So you can't single out
24 auditing.

1 BY MR. COMBS:

2 Q. And would it be possible for
3 another person with your same skill set
4 to look at these documents and these
5 guide and come up with a different
6 opinion?

7 A. I'm sure it's possible.

8 Q. I mean, someone that also
9 was an auditor and also a person that was
10 involved in design control could review
11 these materials and come to a different
12 conclusion.

13 A. Well, these are generally
14 accepted principles based on standards.
15 So this is pretty cut and dry.

16 The standards have been out
17 there forever. Actually, I was looking
18 at one of them, it was like the time I
19 was born these standards have been out
20 there.

21 So it's pretty much just the
22 standards state of the art in the
23 industry for medical devices. Let me
24 qualify. It's for medical devices only.

1 Q. And people in your field can
2 have different opinions on these topics,
3 can't they?

4 A. I'm sure they can.

5 Q. And, for example, many of
6 the topics that you have opined about in
7 your report are things that regulatory
8 and quality professionals at Ethicon
9 considered and came to different
10 conclusions, didn't they?

11 MR. WALLACE: Objection to
12 form.

13 THE WITNESS: Could you
14 restate that. I'm not sure that
15 was a question. It sounded like a
16 statement to me.

17 BY MR. COMBS:

18 Q. That's not a statement, it's
19 a question.

20 A. Okay.

21 Q. I mean, many of the things
22 that you opined upon in your report --

23 A. Okay.

24 Q. -- those same issues were

1 considered by Ethicon, by the regulatory
2 professionals, the quality management
3 professionals at Ethicon, and they came
4 to different conclusions, didn't they?

5 MR. WALLACE: Objection to
6 form.

7 THE WITNESS: To -- who are
8 you speaking about?

9 Are you speaking about
10 Ms. Duncan's report or --

11 BY MR. COMBS:

12 Q. No. I'm talking about the
13 people that work at Ethicon, the people
14 that took the actions that you're
15 criticizing in your report.

16 Those people considered the
17 same materials and came to different
18 conclusions, didn't they?

19 MR. WALLACE: Objection to
20 form.

21 THE WITNESS: I don't know.

22 I can't say what they concluded.

23 I can't say what they reviewed.

24 I -- I'm not them. I have no way

1 to say what they thought.

2 BY MR. COMBS:

3 Q. So no part of your opinion
4 is premised upon conclusions made by
5 Ethicon regarding these issues.

6 MR. WALLACE: Objection to
7 form. Misstates testimony.

8 THE WITNESS: Could you
9 re-ask the question. When you
10 said "no part," I got sidetracked.

11 BY MR. COMBS:

12 Q. Okay. Is any part of your
13 report premised upon the conclusions and
14 actions taken by the employees of
15 Ethicon?

16 A. My report is based upon my
17 knowledge of the industry and the
18 standards and generally accepted
19 principles thereof.

20 Q. And was any part of the
21 factual background for your opinion based
22 upon conclusions drawn by the employees
23 of Ethicon?

24 MR. WALLACE: Objection to

1 form.

2 THE WITNESS: My opinion was
3 based upon review of the documents
4 that I saw, as well as my
5 experience in the industry,
6 generally accepted practices, and
7 current standards as well as
8 review of past standards.

9 BY MR. COMBS:

10 Q. Have you spoken with any
11 other professionals about any of the
12 issues that are contained in your report?

13 A. No, sir.

14 Q. Have you spoken with any
15 regulatory bodies about any of the issues
16 contained in your report?

17 A. No, sir.

18 Q. Have you spoken with any
19 auditors about any of the issues
20 contained in your report?

21 A. No, sir.

22 Q. Were all of the opinions
23 that were contained in your report
24 developed specifically for this

1 litigation?

2 A. Could you restate that.

3 Q. The opinions contained
4 within your report, were they developed
5 specifically for this litigation?

6 A. Yeah. My opinions in this
7 report was developed specifically for
8 this litigation based on these documents.

9 Q. I mean, that was the purpose
10 of your report.

11 A. Yes.

12 Q. Ms. Wilson, I saw that your
13 undergraduate work was done at
14 Vanderbilt.

15 Did you have any contact
16 with Drs. Guelcher or Dunn during that
17 time?

18 A. No, sir.

19 Q. Do you know Dr. Guelcher?

20 A. Never heard of him or her.

21 Q. Do you know Dr. Dunn?

22 A. No, sir.

23 Q. On page 2 of your report,
24 you say that you were asked to address

1 the design control and risk management
2 processes of Ethicon associated with the
3 manufacture of TVT.

4 Is that an accurate
5 statement of what you were asked to do?

6 A. Yes.

7 Q. You don't want to change
8 that in any way?

9 A. No.

10 Q. In your report, you say that
11 you've done 30-plus regulatory
12 submissions.

13 Did any part --

14 A. Whoa, whoa, whoa.

15 MR. WALLACE: I'm sorry.

16 Are you referring to --

17 BY MR. COMBS:

18 Q. "I have been involved in
19 over 30 510k applications and am familiar
20 with the requirements related to FDA
21 clearance of a medical device."

22 A. Okay. Could you restate
23 your question, because those two didn't
24 jive in my mind right at the moment.

1 Q. Okay. In your report you
2 state, "I have been involved in over 30
3 510k and am familiar with the
4 requirements relating to FDA clearance of
5 a medical device."

6 That's what you're saying in
7 your report.

8 A. And further, the next
9 statement says that this is not the topic
10 of this report.

11 Q. Oh, I understand that's
12 what --

13 A. So that is true.

14 Q. I understand that's what you
15 say.

16 Were any of the materials
17 that you considered in forming this
18 report, materials that would also be part
19 of regulatory submissions in relation to
20 these products?

21 A. I did not look at any
22 regulatory submission documents.

23 Q. But that wasn't my question.
24 Would any of the documents

1 you looked at be part of regulatory
2 submissions in relation to these
3 products?

4 A. I'm not sure I can answer
5 this. I have to go back through all of
6 the documents and see if they would be,
7 because I wasn't looking at it from a
8 regulatory submission aspect at all.

9 So that would take
10 considerable amount of work to go back
11 and look at those documents and see if or
12 if not they were would be part of that.

13 Q. Well, for example, you have
14 looked at several clinical expert
15 reports, I mean, there were -- at least
16 there's several on your reliance list.

17 That's part of a regulatory
18 submission, isn't it?

19 A. Not in the experience.

20 Q. It's your experience that a
21 clinical expert report is not part of a
22 regulatory submission?

23 MR. WALLACE: Objection to
24 form.

1 THE WITNESS: Are you
2 talking a 510k?

3 I think I need more
4 information before I can answer
5 that question.

6 A regulatory submission is a
7 very, very broad statement.
8 There's different countries.
9 There's different -- you know,
10 there's U.S. There's EU. There's
11 Japan. There's India.

12 I just don't know to what
13 you're speaking.

14 BY MR. COMBS:

15 Q. Do you know if the clinical
16 expert reports that you reviewed, the two
17 of them that are on your reliance list,
18 do you know whether those were part of
19 regulatory submissions?

20 A. I have no idea.

21 Q. You looked at several CE
22 mark technical files.

23 Is that a regulatory
24 submission?

1 A. To whom?

2 Q. To a notified body?

3 A. Oh, you're not asking me.

4 That's not -- I don't -- that's a totally
5 different question.

6 Q. Okay. Well, that's the
7 question.

8 A. What you started with is
9 saying that I was familiar with 510k
10 processes. And I asked to clarify to
11 whom over and over again.

12 Now, if you are asking me a
13 different question, that's --

14 Q. Ms. Wilson, I'm not trying
15 to trip you up here. If my question is a
16 bad question or an unclear question,
17 okay, just tell me that and we'll start
18 over.

19 A. It's very unclear.

20 Q. Okay, so here's my question.
21 You looked at two clinical
22 expert reports.

23 Are clinical expert reports
24 part of a regulatory submission?

1 A. I can't answer that question
2 without knowing exactly to whom.

3 Q. Okay. You looked at two CE
4 mark technical files.

5 Is that a regulatory
6 submission?

7 A. To whom?

8 Q. To the notified body.

9 A. The notified body may look
10 at a technical file.

11 Q. Yes. That's the purpose of
12 a technical file, isn't it?

13 A. Yes.

14 Q. I mean, that's --

15 A. But I was not asked to look
16 at any submissions. So I don't feel
17 comfortable talking about any
18 submissions. I was asked to look at
19 design control and risk management. And
20 that's my area of expertise.

21 Q. But that's not my question.
22 My question is you have two CE mark
23 technical files on your reliance list.
24 They're part of the materials that you

1 reviewed in forming that opinion.

2 Those two CE mark technical
3 files would be a regulatory submission
4 that was reviewed by a notified body,
5 wouldn't it?

6 A. I'm sure the notified body
7 looked at those technical files, yes.

8 MR. WALLACE: I mean, I
9 would just say for the record that
10 the FDA issue, I believe, has been
11 ruled upon by Judge Goodwin
12 several times.

13 But if you want to go there,
14 of course, that's your prerogative
15 at this point.

16 MR. COMBS: Sure.

17 BY MR. COMBS:

18 Q. And, in fact, that's the
19 whole purpose of the CE mark technical
20 filed being compiled, isn't it, to be
21 reviewed by the notified body?

22 A. I don't see how that has any
23 bearing on what I have been asked to do.
24 I'm just unclear about that.

1 Q. Ms. Wilson, I understand
2 that's your opinion on it.

3 A. Okay.

4 Q. But if you can, answer my
5 question on that.

6 That's why you prepare --

7 A. A technical file --

8 Q. -- a CE mark technical file.

9 A. -- is prepared for a
10 notified body's review. Absolutely.

11 Q. And several of the documents
12 that you relied on in forming your
13 opinion were, in fact, CE mark technical
14 files prepared in relation to TVT.

15 A. They were technical files
16 for review to obtain a C mark. They
17 weren't CE mark technical files.

18 Q. And the CE mark was, in
19 fact, granted for those technical files,
20 wasn't it, for the products that were the
21 subject of the technical file?

22 A. I do not know the answer.
23 I'm assuming so. I didn't look at that
24 aspect. I wasn't looking at CE mark as

1 part of my report.

2 Q. Earlier, I asked you if you
3 had conducted an audit. You told me no.

4 So now I want to ask you
5 about the process that you engaged in.

6 Can you point me to any
7 published standards that would govern the
8 process that you were engaged in to
9 prepare this report.

10 A. Published standards were a
11 part of my knowledge base, but there's
12 not a published standard that I'm aware
13 of that says how to prepare an expert
14 report.

15 Q. And, obviously, I'm not
16 talking about, you know, for example, you
17 have a copy of ISO, you know, 1340. I'm
18 talking about that.

19 I'm talking about any
20 published standards regarding this
21 process which you were engaged in to
22 prepare this report.

23 A. I'm not aware, again, of any
24 standard that says how to prepare an

1 expert report for a medical device
2 company.

3 Q. In regard to what you did in
4 your report, you told me that it's not an
5 audit. So I want to ask you some
6 questions about it.

7 Did you select a single
8 design project to prepare your report?

9 A. Is that the QSIT guide you
10 have got there?

11 Q. Yes.

12 A. Yes, I'm familiar with the
13 QSIT guide.

14 Q. Sure.

15 A. So did I select a single
16 product?

17 Q. Yes.

18 A. The TVT-R is the product.

19 Q. And for the TVT, did you
20 verify that design control procedures
21 that addressed the requirements of
22 Section 820.30 of the regulations had
23 been defined in the document?

24 MR. WALLACE: Objection to

1 form. Outside the report.

2 THE WITNESS: I did not see
3 design control procedures in
4 accordance with 820.30.

5 BY MR. COMBS:

6 Q. Is that part of your
7 analysis in this report?

8 A. I did not see those
9 procedures. And that's related to
10 statements in this report, yes.

11 Q. Does the design control
12 process for TVT comply with 820.30?

13 A. Not to my -- not in my
14 opinion, no.

15 Q. Did you review the design
16 plan for the selected project to
17 understand the layout of the design and
18 development activities?

19 A. I did not see a design plan,
20 to the best of my knowledge.

21 Q. Did you confirm that design
22 inputs were established?

23 A. I did see design inputs.

24 Q. And did those design inputs

1 comply with Section 820.30?

2 A. Not in my opinion, no.

3 Q. Did you verify that design
4 outputs that are essential for the proper
5 function of the device were identified?

6 A. You know, I was told not to
7 go down the FDA path, that this wasn't
8 about the FDA. So I did not look at
9 every single thing in the QSIT guide.

10 That's an inspection
11 technique for the FDA. That is not an
12 audit or a methodology to prepare an
13 expert report. Those are apples and
14 oranges.

15 Q. Did you verify the design
16 outputs that are essential for the proper
17 functioning of the device were
18 identified?

19 MR. WALLACE: Objection to
20 form.

21 THE WITNESS: I did not
22 verify that outputs met inputs. I
23 did not verify each output. I did
24 not do a QSIT inspection.

1 BY MR. COMBS:

2 Q. Did you confirm that
3 acceptance criteria were established
4 prior to the performance of verification
5 of validation activities?

6 A. I did not see those
7 performed prior to verification of
8 validation. No, I did not.

9 Q. Did you confirm that risk
10 analysis was performed?

11 A. At what point in time?

12 Q. Was any risk analysis
13 performed by Ethicon for TVT?

14 A. Yes. And it's stated in my
15 report.

16 Q. Was risk analysis performed
17 by Medscand for TVT?

18 A. Yes. NE [ph] was performed.

19 Q. And so it's your opinion
20 that -- well, what is your opinion?

21 Was the risk analysis
22 performed by Medscand sufficient?

23 A. No, it was not.

24 Q. Was the risk analysis

1 performed by Ethicon sufficient?

2 A. No, it was not.

3 Q. And would that risk analysis
4 have been the subject of the audit
5 conducted by the notified body in regard
6 to TVT?

7 A. I think you have to clarify
8 your question, please.

9 Q. Okay. I'll ask you more
10 about that.

11 Did you determine if design
12 reviews were conducted?

13 A. At what point in time?

14 Q. At any point for TVT.

15 A. At any point in time, yes.

16 Q. Were they, in fact,
17 performed?

18 A. Yes.

19 Q. And did you determine
20 whether design transfer occurred?

21 A. I just don't recall seeing
22 anything, but I wasn't focusing on the
23 FDA 820.30 steps A through, you know,
24 every single input/output, things like

1 that.

2 Q. Those were not steps that
3 you considered in your report.

4 A. Absolutely, I considered
5 them, but I wasn't focused on every
6 single thing, because I wasn't focused
7 specifically on the FDA regulations.

8 Of course, I looked at any
9 documents I had cited in my reports.

10 Q. Your report does not reach a
11 conclusion as to whether this product did
12 or did not comply with Section 820.30,
13 does it?

14 A. I would have to go back
15 through that. But I don't think that I
16 specify 820.30 anywhere in this report.

17 Q. And is it your opinion that
18 this product complies with 21 CFR
19 Section 820.30?

20 A. The TVT-R mechanically cut,
21 as designed, I don't believe fulfills
22 those requirements.

23 Q. And for what reasons?

24 A. They're in my report. Let's

1 go find them.

2 So the original design, it's
3 a requirement in an original design back
4 in the -- I think that that was 1997 to
5 1999. I think Ethicon purchased it
6 around '99. The TVT-R, that's when those
7 design documents should have been, in
8 fact, established.

9 I looked at the design
10 history that was marked as design
11 history, also called the fact book.

12 I looked at the audits that
13 were performed within those.

14 And now I forgot the
15 question. Could you repeat it, please.

16 Q. Yeah. My question was: If
17 you hold the opinion that TVT did not
18 comply with Section 820.30, I want you to
19 tell me why. Why did it not comply?

20 A. Oh, I didn't see design
21 control documents at the point in time it
22 was designed. I didn't see risk
23 analysis, risk -- I saw one application
24 risk analysis. I didn't see a design

1 risk analysis or FMEA done at the time it
2 was designed. I saw subsequent things in
3 2001, 2002.

4 Q. Anything else?

5 A. I saw an audit performed of
6 Medscand by Ethicon that said in '96
7 there were nine major non-conformances
8 including specifications, including
9 design documentation.

10 I would have to look at that
11 exact piece of paper, but they were
12 major.

13 And then there was a
14 follow-up audit in 1998 that said, Oh,
15 well, those nine are fixed, but here's
16 nine more non-conformances.

17 So, to me, it looked like
18 there were still significant issues.

19 Q. When was the design of TVT
20 completed?

21 A. I know it was being sold in
22 Europe in -- can I look at my --

23 Q. Yes.

24 A. -- time line?

1 It says October 1997 it was
2 released in EU. So at that time I would
3 have expected to see design-related
4 documents and risk analyses.

5 And in the U.S., it was in
6 '98. Certainly, by '99, when Ethicon
7 purchased it, there should have been some
8 documents, you know. Perhaps somewhere
9 missing that I didn't see, but I didn't
10 see design risk analysis.

11 Q. All right. Now, the
12 question I had was: When was the TVT
13 design completed?

14 A. I didn't -- I don't know. I
15 didn't see the documents.

16 Q. Did you ask for them?

17 A. I asked for all risk-related
18 documents.

19 Q. How do you define
20 risk-related documents?

21 A. Well, that would be any kind
22 of documents that are as defined in some
23 of the standards. There are EN 1441.
24 There's that whole binder of standards is

1 risk related.

2 The quality standards say
3 that you need to have -- management needs
4 to -- let's back up a little bit.

5 There's always been a
6 requirement for safe and effective
7 products. So that means you have to
8 minimize risk. Every manufacturer has to
9 do that. And that has been as I cite in
10 my report.

11 When I was learning this
12 MIL Q 9858(a), it was back in the 1980s,
13 I was learning it, one of the revisions
14 came out in '63, one of them came out in
15 '59.

16 So this stuff has been a
17 long time coming. This is not anything
18 new.

19 So all of those documents
20 and knowledge about risk and quality
21 systems I used in forming this.

22 And I would have expected to
23 see much more design -- I mean much more
24 risk management to show that this was a

1 safe and reliable product device.

2 Q. Ma'am, here's my question.
3 You said you asked for all risk-related
4 documents.

5 A. I did.

6 Q. What does that include?

7 A. It would include any hazard
8 analysis, HAZOP analysis, risk analysis,
9 risk plans.

10 Q. I'm sorry. You need to slow
11 down. I'm not as fast as you.

12 Hazard analysis?

13 A. HAZOP.

14 And there's an annex in
15 14971 that was also in the predecessor
16 documents. It's also in the textbook in
17 front of you that lists a variety of
18 techniques that can be used to analyze
19 risk.

20 So if we wanted to look at
21 that, we could go ahead and pull that
22 out.

23 Q. And would that include, for
24 example, DDSAs?

1 A. To my knowledge, that must
2 be an Ethicon term. That's not something
3 that is a universal medical device
4 terminology.

5 Q. Is that a risk-related
6 document?

7 A. Yes.

8 Q. You said hazard analysis.
9 Would that include FMEAs?

10 A. A hazard analysis could be
11 an FMEA.

12 Q. What other risk-related
13 documents did you ask for?

14 A. I asked for anything related
15 to risk management or risk analysis.
16 Anything on the topic whatsoever.

17 Q. And are you comfortable that
18 you have all those documents?

19 A. I am not a hundred percent
20 sure. There could always be something
21 out there. There was one thing in
22 Ms. Duncan's report that did not sound
23 familiar to me.

24 Q. And what was that?

1 A. Due Diligence Project Tomlin
2 Checklist [ph]. I don't recall hearing
3 that at all.

4 Q. Other than that, do you
5 believe that you had all of the
6 risk-related documents for TVT?

7 A. To the best of my knowledge,
8 I asked for.

9 Q. Your assumption is that you
10 have all.

11 A. Yeah. My assumption is I
12 do.

13 Q. And if there are any you
14 didn't have, you tried to get them.

15 A. Absolutely.

16 Q. That was part of what you
17 were doing in this process, was trying to
18 assemble all of the risk-related
19 documents in order to form the basis for
20 your opinion?

21 A. Right. I focused on the
22 design.

23 Q. In the United States, is
24 design control governed by 21 CFR 820?

1 A. 820.30, in fact.

2 Q. Ms. Wilson, you told us
3 about 21 820.30.

4 What is that?

5 A. I believe the title is
6 "Design Controls" of the Quality System
7 Regulations.

8 Q. And is 21 CFR 820 the
9 section of federal regulations that are
10 related to medical devices?

11 A. There are many things
12 related to medical devices, so that is a
13 subset.

14 Q. Is it the subset that
15 involves quality system regulations?

16 A. Correct.

17 Q. And so, for example --

18 MR. WALLACE: You have sort
19 of half a question pending. So
20 I'll just note an objection and
21 just ask you to restart.

22 MR. COMBS: Okay. We'll
23 mark this as Exhibit 4.

24 - - -

1 (Whereupon, Exhibit Wilson 4
2 was marked for identification.)

3 - - -

4 BY MR. COMBS:

5 Q. Ms. Wilson, we'll get you
6 your own copy.

7 A. Would it be okay if I get my
8 reading glasses?

9 Q. Of course.

10 - - -

11 (Whereupon, a discussion was
12 held off the record.)

13 - - -

14 BY MR. COMBS:

15 Q. Ms. Wilson, I think we had a
16 question that got interrupted, so we'll
17 just start back on this.

18 Exhibit 4, that's part of
19 21 CFR 820, isn't it?

20 A. This is some document that
21 says "LexisNexis."

22 Q. And do you see that about
23 halfway down the page it "Section 820.1
24 Scope"?

1 A. Okay. This is what -- this
2 is -- when they added -- I believe this
3 is when they added "Design Controls" to
4 820, and they did do that in 1997.

5 Q. And 21 CFR 820.5 governs the
6 establishment of a quality system for a
7 manufacturer who is selling a medical
8 device in the United States, doesn't it?

9 A. Gosh, I wish I -- can I look
10 through my own little code book? 820.5?

11 MR. WALLACE: You have given
12 her -- she's not familiar
13 with LexisNexis.

14 THE WITNESS: So Michie's
15 code or -- I don't know who Michie
16 is.

17 MR. WALLACE: Can she look
18 at the actual code?

19 MR. COMBS: Yeah, of course.

20 THE WITNESS: I mean, or
21 I'll look if I have my own actual
22 code, but I don't know who Michie
23 is or LexisNexis.

24 BY MR. COMBS:

1 Q. Well, I'll represent to you
2 that that's a service that has legal
3 documents online.

4 A. Okay. Well, I'm not a
5 lawyer, so we -- I'm just going to look
6 if I have any own little code book.

7 And voila, I have the
8 official Code of Federal Regulations.

9 And so may I use this?

10 Q. Of course.

11 A. Now, what was your question
12 again?

13 Q. My question was: Is 820.5
14 the section that establishes the
15 regulations or quality systems for
16 manufacturers that are selling medical
17 devices in the United States?

18 A. Yes. 820.5 says, Each
19 manufacturer shall establish and maintain
20 a quality system that is appropriate for
21 the specific medicinal device -- sorry --
22 medical device designated or manufactured
23 and that meets the requirements of this
24 part.

1 Q. And one of the things that's
2 the subject of your report is whether
3 Ethicon's quality system for TVT is
4 adequate, isn't it?

5 A. Not -- I did not look
6 specifically with respect to the FDA, but
7 I did look at the adequacy of the quality
8 management system.

9 Q. And that's one of the things
10 your opining on in this case.

11 A. Not specifically with the
12 FDA, but yes.

13 Q. And one of the things that
14 you're opining on in this case is
15 Ethicon's design controls, isn't it?

16 A. Yes, sir.

17 Q. And it's your opinion that
18 Ethicon's design controls are inadequate,
19 isn't it?

20 A. From what I saw, I believe
21 them to be inadequate for the TVT-R
22 mechanically cut mesh.

23 Q. And 21 CFR 820.30 is the
24 federal regulation that sets the

1 standards for design controls for medical
2 device manufacturers that are selling
3 medical devices in the United States,
4 doesn't it?

5 A. 820.30, right here, is
6 entitled "Design Controls." And it's in
7 21 CFR 820. Yes.

8 Q. And, A, it says, General,
9 Each manufacturer, and then, a Class II
10 device.

11 Ethicon is a manufacturer of
12 TVT, isn't it?

13 A. Yes.

14 Q. TVT is a Class II device?

15 A. My understanding, yes.

16 Q. Do you know whether a TVT is
17 a Class II device?

18 A. Yes.

19 Q. Do you know what it is in
20 Europe?

21 A. I don't. I was not looking
22 at the regulatory pathways.

23 Q. All right. And what it says
24 is, Shall establish and maintain

1 procedures to control the design of the
2 device in order to ensure the specified
3 design requirements are met.

4 That's in 820.30 (a) isn't
5 it?

6 A. Yes.

7 Q. And 820.30 includes sections
8 on design and development planning,
9 design input, design output, design
10 review, design verification, design
11 validation, design history files, doesn't
12 it?

13 A. It does say, in design
14 review.

15 The design history files is
16 in a different section of the
17 regulations, it's back here under
18 records.

19 So the device history record
20 is not discussed until 8 -- oh, that's
21 the device history file.

22 So the design history file,
23 excuse me, is called out in 820.30.

24 Q. And if we can just go back

1 to my question, the question I asked you
2 was: 820.30 establishes requirements
3 regarding it has subsections.

4 A. Right.

5 Q. The subsections include
6 design and development planning, design
7 input, design output, design review,
8 design verification, design validation,
9 design transfer, design changes, and
10 design history files, don't they.

11 A. Yes.

12 MR. WALLACE: Objection to
13 form.

14 BY MR. COMBS:

15 Q. And in your opinion in this
16 case, you're opining on matters that are
17 covered by 820.30, aren't you?

18 MR. WALLACE: Objection to
19 form.

20 THE WITNESS: I'm looking at
21 also things that are in 13485
22 which covers 90 percent of the
23 same.

24 If you looked at -- if you

1 opened ISO 13485, it also talks
2 about those same things.

3 BY MR. COMBS:

4 Q. Okay. But --

5 A. So I'm talking about in
6 general regulatory quality management
7 system requirements. So it's not
8 specific to 820.30.

9 Q. But that wasn't my question.
10 You have opinions in your
11 report that relate to the subjects that
12 are regulated by 820.30, don't you?

13 MR. WALLACE: Objection to
14 form.

15 THE WITNESS: I have talked
16 about design control in my report
17 and I have cited 13485. I have
18 not been talking about 820.30.

19 BY MR. COMBS:

20 Q. I understand.

21 A. They have the same topics,
22 though.

23 Is that what you're asking?

24 Q. And so the topics that for

1 example -- okay.

2 A. Could we just pull that out?

3 Q. No. No. What I'm -- we're
4 talking about 820.30.

5 A. All right.

6 Q. The issues that you're
7 opining on in your report are also
8 addressed by 820.30, aren't they?

9 MR. WALLACE: Objection to
10 form. Argumentative.

11 THE WITNESS: The 13485 and
12 21 CFR 820 Design Controls are
13 approximately the same.

14 I'd have to compare them
15 word to word to tell you what
16 differences there are.

17 BY MR. COMBS:

18 Q. But, again, that's not my
19 question.

20 I mean, my question is: You
21 have opinions regarding design controls.

22 A. Absolutely.

23 Q. And you have opinions
24 regarding risk analysis, don't you --

1 A. Yes.

2 Q. -- in this case?

3 So, for example, you have
4 opinions that Ethicon's design controls
5 were inadequate, don't you?

6 A. Yes.

7 Q. You have opinions that
8 Ethicon's risk analysis related to TVT
9 was inadequate, don't you?

10 A. Yes.

11 Q. You have opinions that the
12 documentation in the design history file
13 was inadequate for TVT, don't you?

14 A. I don't believe I said that
15 exactly in my report.

16 Q. Okay. Well, let's start
17 with you have --

18 A. I think that was not quite
19 what I put in my report.

20 Q. All right. So you have --
21 so is it your opinion that the design
22 history file for TVT was adequate?

23 A. No. That's not also what I
24 said.

1 Q. Okay. You would agree with
2 me that design controls are a subject
3 that is regulated by 820.30, wouldn't
4 you?

5 A. Yes.

6 Q. And you would agree with me
7 that risk analysis for medical devices
8 sold in the United States is a subject of
9 your report, wouldn't you?

10 MR. WALLACE: Objection to
11 form.

12 THE WITNESS: Could you
13 re-ask that question.

14 BY MR. COMBS:

15 Q. You would agree with me that
16 risk analysis is one of the subjects of
17 your report.

18 A. It is one of the subjects of
19 my report, true.

20 Q. And risk analysis is also
21 regulated by 820.30 subsection (g), isn't
22 it?

23 MR. WALLACE: Objection to
24 form.

1 THE WITNESS: That is not
2 specifically true.

3 BY MR. COMBS:

4 Q. So is it your opinion that
5 risk analysis is not governed -- strike
6 that.

7 For a manufacture in the
8 United States that's selling medical
9 devices in the United States, is it your
10 opinion that risk analysis is not
11 governed by 820.30 subsection (g)?

12 MR. WALLACE: Objection to
13 form.

14 THE WITNESS: It says right
15 in subsection (g) the words "risk
16 analysis." So...

17 BY MR. COMBS:

18 Q. I mean, that's one of the
19 subjects that's regulated by the FDA in
20 820.30 subsection (g), isn't it?

21 MR. WALLACE: Objection to
22 form.

23 THE WITNESS: In 820.30
24 subsection (g), it talks -- in

1 Design Validation, it does talk
2 about risk analysis.

3 BY MR. COMBS:

4 Q. And 820.30 subsection (j)
5 addresses design history file, doesn't
6 it.

7 A. Yes, it does.

8 Q. That's one of the subjects
9 that's regulated by the FDA through
10 820.30, isn't it --

11 MR. WALLACE: Objection.

12 BY MR. COMBS:

13 Q. -- the adequacy of the
14 design history file?

15 MR. WALLACE: Objection to
16 form.

17 THE WITNESS: The FDA does
18 say that you shall establish a
19 design history file, and so does
20 the -- and so do the international
21 regulations. They just don't use
22 the exact same words.

23 BY MR. COMBS:

24 Q. And the place where the FDA

1 says that is what we marked as Exhibit 4,
2 it's the 820.30 subsection (j), isn't it,
3 Design History File, Each manufacturer
4 shall establish and maintain a DHF for
5 each type of device?

6 MR. WALLACE: Objection to
7 form.

8 THE WITNESS: It does say
9 that, yes.

10 BY MR. COMBS:

11 Q. But my question was: That's
12 the regulation by which the FDA is
13 regulating design history files, isn't
14 it?

15 MR. WALLACE: Objection to
16 form.

17 THE WITNESS: Yes. This is
18 the Code of Federal Regulation.
19 In the Code of Federal Regulation,
20 820.30 (j), the topic is Design
21 History File.

22 I don't know how much more
23 clear I can be.

24 BY MR. COMBS:

1 Q. Okay. And design control
2 risk analysis and design history files
3 are all regulated through that
4 provision --

5 MR. WALLACE: Objection to
6 form.

7 BY MR. COMBS:

8 Q. -- in United States, aren't
9 they?

10 MR. WALLACE: Objection to
11 form. Asked and answered.

12 THE WITNESS: I believe I
13 have answered that several times.

14 BY MR. COMBS:

15 Q. Okay. Then the answer is
16 yes.

17 MR. WALLACE: Objection to
18 form.

19 THE WITNESS: There are
20 many, many places that risk
21 analysis is also called out in the
22 preamble of the Code of Federal
23 Regulations, and not just
24 narrowly.

1 Those are the only two words
2 that made it into the final, but
3 there's many times in the preamble
4 that it talks about risk.

5 BY MR. COMBS:

6 Q. So there are other federal
7 regulations that also --

8 A. In the preamble. That is
9 not the actual code, but this is -- those
10 are the two words that got into the code
11 under quality management systems.

12 Q. And is the -- strike that.
13 And --

14 A. And ISO 14971 is a
15 harmonized standard. So to isolate it as
16 such is challenging.

17 MR. WALLACE: Can we take a
18 break now?

19 MR. COMBS: Let's just
20 finish this question.

21 BY MR. COMBS:

22 Q. I just want to ask this
23 question to make sure that we're clear on
24 this.

1 Design controls risk
2 analysis and design history file are all
3 regulated in 820.30, aren't they?

4 MR. WALLACE: Objection to
5 form.

6 THE WITNESS: They are.

7 MR. COMBS: We'll take a
8 break now.

9 THE WITNESS: Please.

10 - - -

11 (Whereupon, a brief recess
12 was taken from 10:33 a.m. to 10:46
13 a.m.)

14 - - -

15 BY MR. COMBS:

16 Q. Ms. Wilson, have you
17 reviewed any of the documents that were
18 referenced in Ms. Duncan's report, I
19 mean, other than the ones that were on
20 your reliance list?

21 A. I'm sorry. I really
22 couldn't hear you.

23 Q. I'm sorry. I can be kind of
24 quiet sometimes.

1 You told us earlier -- and
2 we marked as Exhibit 3 Ms. Duncan's
3 report.

4 A. Right.

5 Q. Did you review any documents
6 that were cited in Ms. Duncan's report
7 that weren't on your reliance list?

8 A. Not to my knowledge.

9 Q. I wanted to ask you a
10 question about when the design for TVT-R
11 was completed.

12 Do you remember I asked you
13 that question, you said you didn't
14 remember exactly when?

15 A. I don't believe that was my
16 answer.

17 Q. Well, I'm paraphrasing.

18 Do you remember whether the
19 TVT-R design was completed?

20 A. I said I don't know, because
21 I didn't see those documents, that I'm
22 aware of.

23 Q. And here's what I wanted to
24 ask you.

1 Does the fact that the audit
2 was completed in 1996, would that
3 indicate that the design was completed at
4 the time that the audit was conducted?

5 A. What audit are you speaking
6 of?

7 Q. I'm talking about the audit
8 that Johnson & Johnson's quality
9 assurances department performed on
10 Medscand and which they reported
11 December 12th, 1996?

12 A. Not necessarily. Those are
13 not necessarily the same.

14 Q. Do you know whether the
15 design was completed at the time that
16 audit was performed?

17 A. I don't know.

18 Q. Ms. Wilson, what -- strike
19 that.

20 In the reports -- strike
21 that.

22 In the standards that you
23 relied on, where in those standards does
24 it establish the requirement that a

1 design history file be maintained?

2 A. They just call it something
3 different. There's a requirement that
4 there's a compilation of all the
5 documents relating to the specific device
6 design.

7 Q. And --

8 A. I could show you, if I
9 could open this.

10 Q. Yeah, sure. I would like to
11 know what you're referring to.

12 A. Sure. Is there a specific
13 year or time frame you're talking about?

14 Q. Well, in your report, you
15 said that, In April of 1999, Ethicon
16 purchased Medscand. I reviewed the
17 design history file, also known as TVT
18 fact book and found it to be lacking
19 critical documentation.

20 So let's start with in 1999.
21 What was the requirement that set forth
22 that a company had to have a design
23 history file?

24 A. Well, any of the quality

1 management system standards.

2 Q. And before you do that, let
3 me just make sure that I understand.

4 Are the words "design
5 history file" actually used in these
6 standards?

7 A. No. It's the same intent,
8 same content, but the words "design
9 history files" were used by Johnson &
10 Johnson in that audit, and it was found
11 deficient in 1996.

12 And they were also used in
13 the fact book. It says, "design
14 history."

15 And in that audit, it said,
16 "Design history file."

17 So I used the terminology
18 used.

19 It is a requirement of the
20 exact same, you know, requirements.

21 Q. And I just want to make sure
22 I understand.

23 Is basically the compilation
24 of documents that's referenced in the

1 international standards that you're
2 looking at right now, is that basically
3 the same as the design history file?

4 A. May I show you?

5 Q. Yes.

6 A. I thought that's what you
7 asked.

8 I'm just going through the
9 sections of the planning inputs, outputs,
10 review, verification, validation. I'm
11 trying to locate the specific.

12 It's in the documentation
13 requirement, in Section 4.2. And if you
14 look in the blue text, that will show you
15 where it is.

16 Q. And just so the record will
17 be clear, what you're referring to is
18 International Standard 13485:2003 (e).

19 And you're looking at 4.2.2.

20 A. I think it's 4.2.1.

21 Q. Okay. Sorry.

22 And you're referring us to
23 subsection (f) of that.

24 A. That's -- yeah. But all of

1 these documents, and that's the specific
2 that says for a specific product.

3 Q. And it's your testimony that
4 a compilation of documents that is
5 discussed in that regulation is
6 essentially the same as the DHF.

7 A. Right. And then you go into
8 the design controls in the same sections.
9 You know. It talks about planning,
10 inputs, outputs, design reviews.

11 And those records, it refers
12 back to this section in 4.2 to say that,
13 yes, you need to keep those documents.

14 So throughout, as you go
15 through the design control aspect of this
16 standard -- may I show you?

17 Q. Yes.

18 A. It just says and -- and
19 that's 7.3.

20 If you go through 7.3, say
21 Design Review, for example, which is
22 7.3.4., Record of the results of these
23 reviews and necessary actions shall be
24 maintained. And it says that throughout.

1 So it points you back to
2 that section of 4.2.

3 Q. So as a technical matter,
4 Medscand would not have had a requirement
5 to have a design history file, because it
6 wasn't an American manufacturer, but you
7 are saying that the equivalent of that is
8 imposed with ISO 13485.

9 A. It's -- it's -- yeah. It's
10 the same thing.

11 Q. And a compilation of
12 documents is what is meant by the design
13 history file requirement in 820.30 (j).

14 A. All of the standards require
15 that manufacturers -- I mean, we don't
16 need anything to do with the FDA. This
17 is a standard that certainly says that
18 you have to keep the history and the
19 specifications associated with a product.

20 Q. Now, would you agree that
21 the reason that companies comply with ISO
22 standards is to comply with regulatory
23 requirements?

24 A. Well, they have to -- to get

1 their products on the market, it's the
2 path of least resistance, may I say.
3 That's what the notified bodies are
4 expecting.

5 So, right. So if you want
6 to be a player in the medical device
7 field, you need to have a quality
8 management system.

9 Q. And, companies -- strike
10 that.

11 The ISO standards,
12 themselves, are intended to be used by
13 regulatory bodies, aren't they?

14 MR. WALLACE: Objection to
15 form.

16 THE WITNESS: That's one
17 way. You don't have to use those
18 standards. You can come up with
19 your own method.

20 But if you do you use those
21 international standards, then
22 you're basically -- the
23 presumption is conformance. So
24 that's what your notified bodies

1 are used to looking at.

2 So if you want to make your
3 own up, you can. It's just...

4 BY MR. COMBS:

5 Q. And that was the impetus for
6 creating the ISO standards, was to have a
7 set of standards that could be used for
8 regulation of devices in Europe.

9 A. It was to set forth a
10 standard set of quality management
11 systems, so people would know what they
12 were supposed to do.

13 Q. For the purposes of
14 marketing devices in Europe.

15 MR. WALLACE: Objection to
16 form.

17 THE WITNESS: This isn't
18 just for Europe, but it is for --
19 it's used pretty much throughout
20 the world.

21 BY MR. COMBS:

22 Q. One of the standards that
23 you reference in your report is

24 BS EN 1441 --

1 A. Correct.

2 Q. -- isn't it?

3 Now, that standard was
4 initiated pursuant to a directive from
5 the EU Council Directive, wasn't it?

6 A. The EN standards are all
7 initiated from the EU Council Directive,
8 right.

9 Q. And just to make sure
10 everybody understands, the EU Council
11 Directive, that's the governing
12 regulatory body in Europe, isn't it?

13 A. The EU is the European Union
14 Direct Council, yeah. So it's the
15 committee for the European Union.

16 Q. And the EU Council Directive
17 directed CEN to come up with that
18 standard to be used in European
19 regulatory submissions, didn't it?

20 A. Could you repeat that
21 question.

22 Q. The EU Council Directive
23 directed CEN to write standards,
24 including 1441, that would be used for

1 European regulatory submissions, didn't
2 it?

3 A. All the EN standards do come
4 through that committee and have to do
5 with the medical device central
6 requirements.

7 So the EN -- anything that
8 says EN on it does come through that
9 pathway.

10 Q. So --

11 A. I'm trying to answer your
12 question.

13 Q. You did answer it. Thank
14 you.

15 If it's an EN standard, it
16 was written and established pursuant
17 to --

18 A. The CEN/CENELEC Group.

19 Q. Exactly. The 1993
20 instructions from the Council Directive
21 that go forth and write these standards.

22 A. And then they have to be
23 approved, yes. And they have to be
24 published, and then specific countries

1 can adopt them.

2 Q. Now, the ISO standards that
3 you have referenced, for example, one of
4 them was 13485; is that correct?

5 A. Yes.

6 Q. And 13485 sets forth the
7 medical devices quality management
8 systems requirements for regulatory
9 purposes, doesn't it?

10 A. Yes. That's in the title.

11 Q. And, I mean, that's the
12 purpose of 13485, isn't it?

13 A. I believe I answered what
14 the purpose of 13485 was already, sir.

15 Q. All right. In your report
16 at page 4, subsection 1, you give the
17 title of ISO 13485, don't you?

18 A. Yes.

19 Q. And the title that is
20 ISO 13485 - Medical Devices Quality
21 Management Systems, Requirements for
22 Regulatory Purposes, isn't it?

23 A. Yes.

24 Q. And in the scope of 13485,

1 it states, This international standard
2 specifies requirements for quality
3 management system where an organization
4 needs to demonstrate its ability to
5 provide medical devices and related
6 services to consistently meet customer
7 requirements and regulatory requirements
8 applicable to medical devices and related
9 services, doesn't it?

10 A. May I look at my copy?

11 Q. Sure.

12 A. I have the EN ISO version
13 here. Let's see.

14 And you were reading the --

15 Q. The scope. Scope 1.1.

16 A. Okay. It does say that.

17 Q. And, in fact, throughout
18 13485, it talks about regulatory
19 requirements, doesn't it?

20 A. Yes. That's -- that's what
21 it says.

22 Do you know the reason that
23 it's that way?

24 Q. You know, I'm sure --

1 A. You don't want to know.

2 Q. I'm sure Mr. Wallace will
3 ask you a lot of questions.

4 One of the other standards
5 that you discuss in your report is 14971,
6 isn't it?

7 A. Yes. Several versions are
8 out here.

9 Q. Is it correct that the
10 purpose of 14971 was, quote, A standard
11 for the application of risk management to
12 medical devices became important largely
13 because of the increased recognition by
14 regulators that the manufacturers should
15 apply risk management to medical devices.

16 No medical device risk
17 management standard existed, and ISO
18 14971 was written to fill that gap.

19 A. Where are you reading from?
20 Because there have been many standards
21 about risk over the years.

22 Q. Okay. So --

23 A. And I cited EN 1441 and
24 before that there were others.

1 MR. COMBS: We'll mark this
2 as 5.

3 - - -

4 (Whereupon, Exhibit Wilson 5
5 was marked for identification.)

6 - - -

7 BY MR. COMBS:

8 Q. On page X, at the bottom --

9 A. So now we're looking at the
10 American version of an ISO standard --

11 Q. Okay.

12 A. -- which I did not look at
13 the American version in preparation of
14 this report.

15 Q. Were you looking at the
16 European version?

17 A. I was looking at the ISO and
18 EN ISO versions, because that was the
19 focus. I'm not sure it matters, but --

20 Q. And EN is what you told us
21 about earlier. That would be the
22 standards that were done, pursuant to the
23 EU Council Directive?

24 A. That's right.

1 Q. Page X.

2 A. Here it is.

3 Q. And just it was the first
4 two sentences of that.

5 A. (Witness reviewing
6 document.)

7 Well, it was an EN standard
8 about risk management prior to ISO 14971.

9 So the fact that there was
10 none, I don't believe to be true. There
11 is -- maybe there was not an ISO made by
12 a working group, but if you look in this
13 binder, there's the EN 1441.

14 Q. And that's what we talked --

15 A. That is cited in the Ethicon
16 procedures and in the other report.

17 Q. And that's the standard that
18 we talked about earlier, the one --

19 A. Yeah.

20 Q. -- done pursuant to the EU
21 Council Directive.

22 A. Yeah. It's an EN standard.

23 Q. And so here, in the
24 introduction, what they say is that 14971

1 was written because of increased
2 recognition by regulators, that the
3 manufacturer should apply risk management
4 to medical devices, no medical device
5 risk management standard existed, and ISO
6 14971 was written to fill that gap.

7 A. That's what it says, yes.

8 Q. And you disagree with that?

9 A. I'm just saying that there
10 are other standards and there always have
11 been related to safety and reliability.

12 I have worked in -- I
13 remember working in oximeters, and we did
14 all kinds of stress screening and we did
15 mill standard evaluation and capacitor
16 de-rating, all kinds of things for safety
17 and reliability, and those kind of
18 things, regardless of -- and there were
19 increasing number of issues that were
20 coming up in the time frame of the first
21 14971-1.

22 So that could have been what
23 they were referring to. But there always
24 have been standards out there.

1 Q. And what they're saying is
2 that the impetus to write 14971 was to
3 provide additional standard for
4 regulators.

5 A. Yeah. I can't speak to the
6 impetus for regulators. I'm not a
7 regulator.

8 Q. Ms. Wilson, as part of the
9 process of receiving the CE mark,
10 Medscand and then Ethicon would have been
11 inspected by a notified body, wouldn't
12 it?

13 A. You do need to have a
14 notified body come in and look at your
15 quality management system.

16 Q. And as part of that, the
17 notified body conducts an audit, doesn't
18 it?

19 A. They do.

20 Q. And one of the things the
21 notified body does is determine whether
22 the manufacturer is complying with
23 international standards, isn't it?

24 A. But the notified -- QA

1 Consulting is certified to ISO 13485 with
2 ISO 9001. So we do have auditors come in
3 and look at our system.

4 And what they do is they
5 come in and make an assessment based on
6 your procedures and some records to make
7 their best determination at a given point
8 in time whether you complied with those
9 regulations.

10 Q. And, in fact, you know that
11 Medscand was audited by the notified
12 body, wasn't it?

13 A. May I look at that document?

14 Q. Yes.

15 MR. COMBS: We'll mark this
16 as 6.

17 THE WITNESS: I don't
18 remember the clear -- actually
19 took place and the address and
20 stuff.

21 So I may have to look at
22 that.

23 - - -

24 (Whereupon, Exhibit Wilson 6

1 was marked for identification.)

2 - - -

3 BY MR. COMBS:

4 Q. Ms. Wilson, here's a copy
5 for you.

6 A. Thank you.

7 1997 to '99. Okay. This
8 was -- oh, I'll read the next page.

9 I did not look at this
10 Annex A to that, or I don't remember
11 looking at the Annex A or anything about
12 the you Cytobrush.

13 Okay.

14 Q. Did you have a chance to
15 review Exhibit 6?

16 A. I looked at the parts
17 relating to the TVT, not the Uterobrush
18 or whatever.

19 Q. And on the first page of
20 Exhibit 6, is that an EC certificate?

21 A. Yes.

22 Q. And it was granted to
23 Medscand Medical?

24 A. That's what it says, yes.

1 Q. And Medscand Medical was the
2 manufacturer of TVT?

3 A. In 1997, yes. 1997, it was.

4 Q. And --

5 A. I think that's when they
6 went into their agreement, somewhere in
7 1997.

8 Q. And does the certificate
9 reflect that the certificate was granted
10 and approved in conformity with the
11 requirement of Annex II, Section 3.2,
12 Full Quality Assurance System of Council
13 Directive 93/42/EEC, concerning medical
14 devices?

15 A. That's exactly what it says.

16 Q. And the scope of the
17 certification included the design,
18 manufacture, final inspection, and
19 distribution of the TVT device in
20 Class IIb for tension-free vaginal tape
21 procedure.

22 A. That's what it says.

23 Q. And it was issued on
24 February 10th, 1997, and then revised

1 on --

2 A. I think it was October 2nd.

3 Q. And then revised on
4 September 23, 1999?

5 A. Yeah. I don't -- the
6 revision date says that. I don't see a
7 revised certificate here. Maybe it's
8 here.

9 Q. If you could turn to the
10 fourth page of that.

11 Is that the quality system
12 certificate?

13 A. Yes.

14 Q. And that would have been
15 issued by the Danish regulators --
16 Swedish regulators?

17 A. It's cut off, but DS
18 standard -- Dansk.

19 Q. So the finding of those
20 regulators was that Medscand fulfilled
21 the requirements of DS/EN ISO 9001
22 1994/DS EN ISO 46001:1996?

23 A. Correct.

24 Q. And that finding was in

1 regard to the design manufacturer final
2 inspection and distribution of urinary
3 incontinence instruments including the
4 TVT system?

5 A. And related products.

6 Q. And the entire --

7 A. And single-use medical
8 devices for sampling of cells, tissues,
9 body fluids, and hereto-related products,
10 whatever the hereto-related products are.

11 Q. Okay. And then it says
12 right below, The certificate is granted
13 in conformity with the DS rules for the
14 certification of quality systems?

15 A. It -- yes, it says that.

16 Q. The auditors -- strike that.
17 The regulators that
18 conducted this audit, they came to the
19 conclusion that Medscand was in
20 conformance with the ISO standards at the
21 time that they issued this certificate,
22 didn't they?

23 A. That's what this document
24 says.

1 Q. I mean, that would have been
2 the whole purpose of their review, wasn't
3 it?

4 MR. WALLACE: Objection to
5 form.

6 THE WITNESS: Could you
7 restate that question.

8 BY MR. COMBS:

9 Q. The regulators, the purpose
10 of their review would have been to see if
11 Medscand complied with the ISO standards.

12 A. The purpose of any review --
13 the whole purpose would not be just to do
14 that, no.

15 Q. Would that be a purpose?

16 A. A purpose, yes.

17 Q. Would that be one of the
18 tasks that they engaged in during this
19 audit?

20 A. Could you say the whole
21 question.

22 Q. Yes.

23 A. Thanks.

24 Q. Was one of the jobs that the

1 regulators were doing, to make a
2 determination of whether Medscand
3 complied with the ISO requirements in
4 September of 1999?

5 MR. WALLACE: Objection to
6 form.

7 THE WITNESS: I think it
8 says September of 1997.

9 BY MR. COMBS:

10 Q. Well, on the front, the
11 first page of Exhibit 6, they say it was
12 first issued in October of 1997.

13 A. Okay. So one of -- yes.
14 One of the things that the regulators
15 were looking at would have been
16 compliance to these standards.

17 Q. And it was the regulators'
18 determination that Medscand was in
19 compliance with ISO standards at that
20 time.

21 MR. WALLACE: Objection to
22 form.

23 THE WITNESS: The
24 certificate, Exhibit 6, documents

1 that that's what the regulators
2 found.

3 BY MR. COMBS:

4 Q. And --

5 MR. COMBS: This is
6 Exhibit 7.

7 - - -

8 (Whereupon, Exhibit Wilson 7
9 was marked for identification.)

10 - - -

11 BY MR. COMBS:

12 Q. And I have handed you what's
13 been marked as Exhibit 7 -- or the court
14 reporter has handed you what's been
15 marked Exhibit 7.

16 A. Okay.

17 MR. COMBS: Thank you.

18 BY MR. COMBS:

19 Q. And what's Exhibit 7?

20 A. It says it's a Certificate
21 TUV.

22 Q. And TUV is a notified body,
23 aren't they?

24 A. Yes. It's a different

1 notified body than the prior certificate.

2 Q. And TUV was certifying
3 Ethicon SARL; is that correct?

4 A. Right. I don't know what
5 SARL is, but it's a location of Ethicon,
6 I believe.

7 I don't know where that --
8 it must be in Germany. Neuchatel? I
9 don't know where that is.

10 Q. And at some point in 2000,
11 manufacture of the TVT device was
12 transferred from Medscand to Ethicon,
13 wasn't it?

14 A. I do believe I read that.

15 Q. And after that, after the --
16 strike that.

17 After the manufacturing was
18 transferred to Ethicon, Ethicon had to
19 get certified by the notified body
20 regarding the manufacture of TVT, didn't
21 it?

22 A. I'm not exactly sure how
23 that works for new products within an
24 existing qualified facility.

1 But I -- to be honest, it
2 looks like they had one. I don't know if
3 it was part of their routine one or if it
4 was because they moved a new product.

5 So I can't answer your
6 question directly.

7 Q. And what TUV did was they
8 conducted an audit of urinary stress
9 incontinence device TVT and accessories,
10 didn't they?

11 A. That's what it says here,
12 yes.

13 Q. And they were auditing
14 Ethicon SARL?

15 A. That's what it says.

16 Q. And the notified body
17 concluded that Ethicon SARL in relation
18 to TVT had established and is maintaining
19 a quality system which meets the
20 requirements of the EN 460061:1996 and
21 includes ISO 9001:1994, didn't they?

22 A. Yeah. That's what this
23 says.

24 You know, as part of a

1 consultant, I have seen a lot of
2 certificates.

3 One thing that's interesting
4 is you can have these, but that doesn't
5 mean that everything is exactly working
6 as intended.

7 Q. Okay. And that was the
8 conclusion drawn by the regulators --

9 A. Correct.

10 Q. -- at TUV, wasn't it?

11 MR. WALLACE: Objection to
12 form.

13 BY MR. COMBS:

14 Q. And if you turn the page --
15 turn it over -- on the second page, the
16 regulators state that, For the
17 products/product categories: Urinary
18 stress incontinence TVT device, quote,
19 Maintains a quality system, which ensures
20 that the product conforms with the
21 essential requirements of the Directive,
22 which apply to them at every stage from
23 design to final controls, doesn't it?

24 MR. WALLACE: Objection to

1 form.

2 THE WITNESS: This does say
3 that. I'm not sure exactly if
4 this was -- what TVT this was.

5 So this was -- but that's
6 what this says, TVT devices.
7 Doesn't say anything about the
8 accessories, though, or the
9 system, so...

10 BY MR. COMBS:

11 Q. It says, For the product
12 categories, quote, urinary stress
13 incontinence (TVT) device.

14 MR. WALLACE: Are you just
15 asking her to say that -- the
16 document says what it says.

17 You can't ask her to
18 interpret a document that you
19 haven't yourself even
20 authenticated.

21 We have no idea where this
22 is coming from.

23 She will agree that the
24 words on the page say what they

1 say, right?

2 MR. COMBS: Okay.

3 MR. WALLACE: I mean, is
4 that what you're asking?

5 MR. COMBS: No.

6 BY MR. COMBS:

7 Q. Are you --

8 A. That's all I'm doing is
9 reading what you're saying and --

10 Q. I understand.

11 A. -- agreeing that this page
12 says exactly what it says.

13 Q. And you told us you have
14 seen these certificates before.

15 A. If these numbers are called
16 out in my numbers, then I probably
17 browsed them.

18 Q. I apologize. That was a bad
19 question. That was not what I was
20 asking.

21 A. That's what I have been
22 doing this whole time is repeating after
23 you, because that's what I thought you
24 were asking me.

1 Q. No. What I was asking was
2 not whether you had seen this specific
3 certificate before.

4 You have reviewed
5 certificates granted by notified bodies
6 before, haven't you?

7 A. I don't think you asked me
8 that. I'm sorry. You could ask, but of
9 course I have seen them, because I am
10 certified, and I said that directly, that
11 our company is 13485 certified, my
12 company, and ISO 9001 certified.

13 Q. And people in the industry
14 rely on these certificates, don't they?

15 MR. WALLACE: Objection to
16 form.

17 THE WITNESS: Some people
18 do.

19 BY MR. COMBS:

20 Q. And, in fact, these
21 certificates establish that the
22 regulators, who inspected both Medscand
23 and Ethicon, came to the conclusion that
24 the TVT device was in compliance with ISO

1 standards, didn't they?

2 MR. WALLACE: Objection to
3 form.

4 THE WITNESS: I don't know
5 what exactly -- I don't know --
6 from this certificate, I don't
7 know what they inspected.

8 In fact, regulators of
9 notified bodies don't inspect.
10 They audit.

11 I have no records of what
12 they audited, what they looked at.
13 I have none of their documents
14 that go with -- each one of these
15 comes with a report, and each
16 report comes with minor
17 non-conformances, major
18 non-conformances, and comments.

19 And then they have to come
20 back every few years.

21 So this certificate in and
22 of itself doesn't tell me very
23 much of -- about any of these
24 audits.

1 BY MR. COMBS:

2 Q. And so we'll look at
3 Exhibit 6. The scope of the
4 certification is design, manufacture,
5 final inspection, and distribution of the
6 TVT device and Class II for tension-free
7 vaginal tape procedure.

8 That's what the scope of the
9 certification is, isn't it?

10 A. Sorry. Where is 6 again?
11 Yikes. Sorry.

12 MR. WALLACE: Just same
13 objection, for the record.

14 THE WITNESS: All I can do
15 is read what the certificate says.

16 MR. COMBS: Sure.

17 THE WITNESS: And the
18 certificate states -- what's your
19 name again? Mr.?

20 MR. COMBS: Philip Combs.

21 THE WITNESS: Mr. Combs.

22 He's reading it, and I'll
23 read the same thing.

24 BY MR. COMBS:

1 Q. Sure. And it says that the
2 scope of the audit included the design
3 and manufacture of TVT.

4 MR. WALLACE: Same
5 objection.

6 I think that's the fourth
7 time you asked that.

8 THE WITNESS: I've already
9 answered that question, sir.

10 BY MR. COMBS:

11 Q. Did you have any information
12 at all in your possession that -- that
13 that was not the scope of that audit?

14 A. I don't have any -- I don't
15 have any knowledge of this audit besides
16 this piece of paper.

17 Each audit comes with an
18 audit report and a checklist. So from
19 this piece of paper, I can't tell you --
20 basically, I can tell you like very, very
21 little about the audit itself.

22 Q. Did you make any efforts to
23 obtain any of the records regarding the
24 audit?

1 A. My topic was not to look at
2 regulatory submissions or anything like
3 that. I was to look at risk documents
4 and to look at design controls.

5 So this really has no
6 bearing on those topics.

7 Q. So is the answer to my
8 question, no, that you made no efforts to
9 obtain the documents that underlay that
10 certificate?

11 MR. WALLACE: Objection to
12 form.

13 THE WITNESS: I did not.
14 BY MR. COMBS:

15 Q. And do you know -- strike
16 that.

17 I want to ask you about
18 TVT's technical files.

19 Do you know what technical
20 files were maintained by Ethicon
21 regarding TVT?

22 A. I believe in my report I
23 cited a technical file for TVT.

24 Q. Do you know whether there

1 were any other technical files maintained
2 by Ethicon for TVT other than the one you
3 cited?

4 A. There were others for
5 different products that were not the
6 scope of my report, yes.

7 Q. And what are those other
8 products?

9 A. I don't have them exactly
10 memorized, because that wasn't in the
11 scope of my report.

12 I think they were -- I just
13 don't have it in my head. I focused in
14 on the TVT-R.

15 I'm just going to grab
16 another water.

17 Q. Yes, of course.

18 Ms. Wilson, in your reliance
19 list, you referenced two clinical expert
20 reports.

21 Did you review any other
22 clinical expert reports prepared by
23 Ethicon related to TVT?

24 A. The only things I would have

1 reviewed were in my reliance list.

2 Q. In your reliance list, you
3 reference review of two CAPAs.

4 What's a CAPA?

5 A. Corrective action/preventive
6 action.

7 Q. Do you know whether there
8 were any other CAPAs performed in regard
9 to TVT?

10 A. I don't know. I don't have
11 the whole list of CAPAs that were
12 performed in a breakdown by product type.

13 Q. So you don't know?

14 A. Could you restate the
15 question.

16 Q. You reviewed two CAPAs. Are
17 those the only two CAPAs that were
18 performed in relation to TVT?

19 A. I don't know.

20 Q. Did you make any effort to
21 obtain other CAPAs performed regarding
22 TVT?

23 A. I did ask for anything
24 related to TVT, CAPAs, risk things,

1 anything related that would have come out
2 of those complaint reviews. So I did ask
3 for those things.

4 Q. And what you received were
5 two.

6 A. I'd have to go look at my
7 reliance list, but I think those are
8 those that are footnoted.

9 I just don't recall every
10 document that I looked at. I'm sorry.

11 Q. Did you review any clinical
12 literature related to TVT?

13 A. Only those things that were
14 cited in my review.

15 Q. So I saw two pieces of
16 medical literature on your reliance list.

17 Would you have review any
18 other medical literature other than those
19 two?

20 A. No, sir. I didn't look at
21 anything that wasn't on that list.

22 Q. So you didn't review any
23 clinical literature regarding Prolene
24 sutures?

1 A. Well, on that list there
2 were documents about Prolene sutures, and
3 I do footnote those.

4 Q. My question -- I'm sorry.
5 My question was: Did you review any
6 clinical literature, any published
7 medical literature regarding Prolene
8 sutures?

9 A. There was a published
10 article on my list, and I believe it's
11 footnoted.

12 Q. What article is that, that
13 you're referring to?

14 A. I'm not sure I brought it
15 with me today or that I would be able to
16 locate it based on the Bates numbers.

17 Let me see what I can do.

18 Are we allowed to pull up a
19 Bates number and see if it's what it
20 might be?

21 Q. Yeah. What footnote is it
22 that you're referring to?

23 A. It could be Footnote 75.

24 Q. And could you tell me the

1 Bates number for that?

2 A. 05845592. I'm not sure, but
3 that's a guess.

4 Q. So that's on page 17.

5 So whatever it is you are
6 referring to, you are referring to
7 Footnote 75.

8 A. Like I said, that's my best
9 estimate. We'll have to check to see if
10 that's correct.

11 Q. Okay. We can check that.

12 Other than that, which might
13 be clinical literature related to Prolene
14 sutures, would you have looked at any
15 other clinical literature related to
16 Prolene sutures?

17 A. Sir, I believe I said if
18 it's on my list, I might have looked at
19 that. I did not go outside and try to
20 locate other clinical literature.

21 Q. So if there's no clinical
22 literature on your list for Prolene
23 hernia mesh, so would that mean you
24 didn't try to go out and get any of that?

1 A. I did not seek out anything
2 that wasn't on my list. This article --
3 these footnotes in the section do talk
4 about sutures and they talk about -- I'd
5 have to go read it. It says right here.

6 Q. Well, is there a difference
7 between an internal company document and
8 peer-reviewed clinical literature?

9 A. Yeah.

10 Q. And so my question is, did
11 you review any peer-reviewed --

12 A. But you're saying clinical
13 literature versus scientific literature.
14 I'm just not sure what you mean by
15 clinical.

16 I mean, there's many
17 scientific journals --

18 Q. Okay.

19 A. -- that may not have
20 anything to do with the clinical aspect.
21 And I can't speak to anything clinical,
22 because I'm not a physician.

23 And I know that I also
24 footnoted that. So I can't make any

1 clinical judgment.

2 So that's why I'm trying to
3 be very clear versus scientific. Or --
4 you know, a presentation can be
5 peer-reviewed.

6 So I'm just really not sure
7 what you're asking.

8 Q. Did you review any
9 preclinical testing that Ethicon did for
10 Prolene sutures?

11 A. Whatever I looked at is
12 footnoted here or in my list. And I did
13 look at some data that showed right here
14 on page 17.

15 It says, A series of
16 internal reports on the outcomes
17 associated with implantation of Prolene
18 sutures in human and canine explant
19 studies.

20 So often canines are used in
21 preclinical animal studies.

22 So if that's what you're
23 referring to, then I did look at some
24 reports on canines.

1 Q. Would you have looked at any
2 other preclinical studies other than
3 what's in that paragraph underneath
4 Degradation on page 17?

5 A. If it's on my list, I would
6 have to go back and check through that
7 whole list to see if there were any
8 others.

9 Q. And if it's not on the list,
10 you didn't look at it.

11 A. No.

12 Q. Did you review the Prolene
13 new drug application?

14 A. I'm sorry. I had so many
15 documents, I just can't remember them
16 all.

17 Did I look at what?

18 Q. The Prolene suture new drug
19 application from 1969.

20 A. No. And I'm not qualified
21 to do anything to do with drugs, only
22 devices.

23 Q. And do you know whether the
24 Prolene suture was first regulated as a

1 drug?

2 MR. WALLACE: Just so
3 we're -- we are now -- go ahead
4 and ask your question, and then
5 we'll --

6 Q. That was the question.

7 MR. WALLACE: You're calling
8 it a drug. Well --

9 THE WITNESS: I have no
10 knowledge of drugs. And I have no
11 knowledge of anything to do with
12 any regulations of drugs. I only
13 work in medical devices.

14 BY MR. COMBS:

15 Q. All right. Prolene
16 suture -- I'm not trying to trip you up
17 or be tricky here at all.

18 Prolene sutures were first
19 approved through an NDA that was in 1969.
20 That's why I ask you that question.

21 A. I'm not aware of that.

22 Q. Okay. When is the first
23 time you ever heard of a TVT device?

24 A. Well, of a specific -- the

1 TVT?

2 Q. Yes, ma'am.

3 A. July.

4 Q. Prior to being engaged in
5 this litigation, you had not heard of
6 TVT.

7 A. Not -- I have heard of mesh,
8 but not TVT, no.

9 Q. And had you heard of
10 midurethral slings?

11 A. I'm sure they have
12 commercials on TV and things like that.
13 I've really never focused on it. I don't
14 have stress urinary incontinence.

15 Q. Do you have any idea how
16 many TVT devices have been implanted?

17 A. I do know that one of the
18 complaint analyses say there were 213,000
19 of them at a given point in time. So I
20 do not know specifically.

21 Q. Have you ever seen a TVT?

22 A. I have seen the IFU for
23 them.

24 Q. Have you ever actually seen

1 a TVT device?

2 A. I saw a YouTube. No, I have
3 not physically held one.

4 Q. Do you understand how to
5 implant a TVT?

6 A. No. I'm not a physician. I
7 have read the IFU, but I think it's
8 clearly stated in my report that I can't
9 comment on anything to do with
10 implantation or physicians.

11 Q. And is that because you're,
12 I mean, obviously not an M.D.?

13 A. No, I'm not.

14 Q. And so in order to be able
15 to comment regarding the implantation or
16 clinical aspects of the device, would you
17 need medical training?

18 MR. WALLACE: Objection to
19 form.

20 THE WITNESS: I can comment
21 as to how it says, you know, to
22 implant it in the IFU, and I can
23 certainly understand from a design
24 control, you know, perspective how

1 you go about doing the design, the
2 development, and the risk
3 management things.

4 So from all those
5 perspectives, I feel very
6 comfortable. But I'm never going
7 to comment on how to physically
8 perform an implant of a device.

9 BY MR. COMBS:

10 Q. Do you know what part of the
11 urethra is supported by TVT?

12 A. I know that the urethra is
13 supported, but I don't know the exact
14 portion. I could read the IFU.

15 Q. Do you know the difference
16 between polypropylene and Prolene?

17 A. Polypropylene is -- Prolene
18 is a polypropylene. I believe that's on
19 page -- let's go back. That's right in
20 the beginning.

21 In the background section,
22 it says, Prolene, polypropylene mesh. So
23 it's a brand name of a polypropylene.

24 Q. And do you know any ways in

1 which Prolene differs from generic
2 polypropylene?

3 A. I don't know the full
4 manufacturing process. I certainly know
5 about extrusions of plastics and poly- --
6 various materials, because I've validated
7 those processes.

8 So I understand how they're
9 formed and how they're measured, and how
10 they're validated, and how they can be
11 cut and hollowed, and those things.

12 So I understand the
13 backgrounds of the plastics, but I'm not
14 a plastics person.

15 Q. So my question was: Do you
16 know what the difference is between
17 Prolene and polypropylene?

18 MR. WALLACE: Objection to
19 form.

20 BY MR. COMBS:

21 Q. Let me start, do you know,
22 is there a difference?

23 A. All I know is that this is a
24 Prolene with a register. So to me that

1 means it's a brand name of a
2 polypropylene.

3 Q. Do you know whether anything
4 is added to the polypropylene in order to
5 make Prolene?

6 A. I do not know the specific
7 formulation of the material, no.

8 Q. Do you know whether the mesh
9 that's in TVT is made of knitted
10 filaments of Prolene?

11 A. That was in a document I
12 read. I would have to go back and review
13 that. But there was a document somewhere
14 that talked about different knitting
15 techniques.

16 Q. And I think you told me
17 earlier, and I don't want to belabor it.

18 I think you told me that you
19 had not worked on any projects that
20 involved polypropylene except for the one
21 where you were the QA monitor for an
22 animal study; is that correct?

23 A. Not that I recall. I know
24 that there was -- there were various

1 plastics in knee inserts, and things like
2 that.

3 I just can't -- I don't
4 think they were polypropylenes. There
5 may have been an instrument handle
6 somewhere, but not an implant.

7 Q. And certainly no work on
8 Prolene implants prior to this project.

9 A. No.

10 Q. And you told us that you're
11 not an M.D. You're also not a polymer
12 scientist, are you?

13 A. No, sir.

14 Q. Are you a biomechanical
15 engineer?

16 A. My degree is in biomedical
17 engineering. Biomechanical, no. Various
18 universities call those various things.
19 That's why I'm being specific.

20 Vanderbilt in the 1980s
21 called it biomedical. Some universities
22 now, they call it different things.

23 Q. If I asked you -- well
24 strike that.

1 What are the different kinds
2 of urinary incontinence?

3 A. I know there's stress
4 urinary incontinence.

5 Q. Do you know what the other
6 kinds of urinary incontinence are?

7 A. I couldn't name them, no.

8 Q. Do you know what causes
9 stress urinary incontinence?

10 A. Yes. I did read that. I'd
11 have to go back and review the documents.

12 It may be in the IFU.

13 Q. As we --

14 A. There were a couple of
15 things that cause that. I'm just not --
16 I didn't focus on the medical aspect,
17 because I was focusing on the design and
18 risk.

19 And as part of any of those,
20 you have a team. And the team consists
21 of someone that's in the medical realm.

22 My expertise is in the
23 design assurance and design control
24 areas. And I have done that for many

1 implantable devices, probably many
2 companies for many years.

3 So there's always been a
4 medical expert M.D., marketing expert,
5 clinical experts that were -- that work,
6 you know, as part of those teams that we
7 would draw from for any of those very
8 specific questions.

9 Q. So the other -- strike that.
10 So when you're working with
11 a team in regard to developing products,
12 the medical questions would be answered
13 through the expertise of the doctor?

14 A. Well, the design engineer.
15 The user requirements define those
16 things. And even the procedures that I
17 have referred to all define -- it's a
18 team approach.

19 But they often have the
20 regulatory or the quality person in
21 charge of those teams. So I would be the
22 person in charge of those teams.

23 Q. But you would not be the
24 person providing the expertise regarding

1 the medical issue.

2 A. No, I would not.

3 Q. So, I mean, somebody --

4 A. We would have --

5 Q. -- else on the team would --

6 A. Right.

7 Q. -- would be tasked with
8 that.

9 A. Right. You know, we would
10 have physicians come in or they would
11 give the user requirements, but I
12 wouldn't be the clinical or the physician
13 expert.

14 Q. Do you know what the
15 alternative procedures for stress urinary
16 incontinence are that the plaintiffs are
17 putting forth as alternatives in this
18 case?

19 A. I did read some of those
20 things. I would have to go back to the
21 documents. I mean, they talked about
22 open procedures as one of them.

23 I'm sure that not having a
24 procedure is an alternative.

1 Q. Do you know what a Burch
2 colposuspension is?

3 A. No. Obviously. Sorry. You
4 can tell by my face.

5 Q. Sure.
6 Do you know what a
7 pubovaginal sling is?

8 A. I'm -- not exactly.

9 Q. Do you know what the risks
10 are of a Burch colposuspension?

11 A. How would I know that if I
12 just told you I didn't know what it was?

13 Q. Do you know what the risks
14 are of a pubovaginal sling?

15 A. If I was in charge of risk
16 management of those devices, I would go
17 through a very specific defined process
18 as required in the regulations and in the
19 standards and in those guidance
20 documents.

21 There's also other things
22 like global harmonized task force
23 guidance documents. So it's not just
24 these.

1 And I would make sure that
2 all those risks were defined as far as
3 reasonably foreseeable risks, and make
4 sure that each and every one of those on
5 a system level as well as component level
6 were addressed.

7 Q. But you haven't done that in
8 preparation for any of the --

9 A. No, sir.

10 Q. And do you know whether --
11 well, strike that.

12 Since you don't know what a
13 Burch colposuspension is, you would not
14 know whether any risk analysis has ever
15 been performed on that procedure, would
16 you?

17 A. No. I was looking at TVT-R
18 mesh.

19 Q. All right. And you would
20 not know whether any risk analysis has
21 ever been performed on a pubovaginal
22 sling, would you?

23 A. My assumption is that all
24 medical device companies would follow the

1 same industry practice, because that's
2 accepted practice.

3 So I would have to assume
4 that they used the proper tools that are
5 in place.

6 Q. If they were a medical
7 device.

8 A. If they were a medical
9 device.

10 If they weren't, then I'm
11 not knowledgeable to talk about it if
12 they're not a medical device.

13 Q. What's the pore size for
14 TVT?

15 A. I'm sure that's written in
16 some of these documents. I think that I
17 don't have that in my head. I do know
18 some documents talked about weights per
19 cubic centimeter or something.

20 I don't know the pore size.
21 It's probably in the many, many pages
22 somewhere.

23 Q. Do you know what the weight
24 is for TVT?

1 A. It, too, is in the documents
2 somewhere.

3 Let's see. It may be
4 footnoted.

5 (Witness reviewing
6 document.)

7 Okay. We would have to --
8 if we looked in Footnote maybe 109 is my
9 best guess of where that might be.

10 Q. For which? For the weight?

11 A. Yeah, for the weight. That
12 would be my best estimate would be --
13 which is on page 20 of my report.

14 I didn't memorize those
15 stats.

16 Q. As we sit here today, do you
17 know whether -- do you know whether --
18 strike that.

19 Do you know whether TVT had
20 the largest pore size of any stress
21 urinary incontinence mesh sold in the
22 United States?

23 A. I don't know. But I do
24 remember that the weight was somewhere, I

1 believe -- well, we could call it up, but
2 I think it was, like, 80 to 110 or 102
3 something per cubic centimeter, but I'd
4 have to go back.

5 I didn't look at pore size,
6 but the weight, when I talked about
7 weight, that would be in the area those
8 footnotes would be.

9 Q. Do you have any patents?

10 A. No, I do not.

11 Q. Okay. Have you ever
12 invented a medical device?

13 A. I'm working on it. No, I do
14 not.

15 Q. Other than the consulting
16 that you've done -- strike that.

17 You have never performed an
18 FMEA for a stress urinary incontinence
19 device, have you?

20 A. No.

21 Q. And you have never performed
22 a DDSA for a stress urinary incontinence
23 device, have you?

24 A. A DDSA is an Ethicon term.

1 I have not performed that.

2 However, I have for about 13
3 other permanently implantable passive
4 medical devices, if not more.

5 Q. And none of those involved
6 the pelvic floor or stress urinary
7 incontinence, did they?

8 A. No, they did not.

9 Q. Ms. Wilson, I asked you
10 earlier about the approval of the NDA for
11 Prolene sutures in 1969, and you told me
12 you were not aware of that.

13 So I just want to ask you to
14 assume that Prolene sutures were approved
15 as part of the NDA in 1969.

16 Is that a fact that Ethicon
17 could rely on in the risk assessment for
18 TVT?

19 MR. WALLACE: Objection to
20 form.

21 THE WITNESS: And that was a
22 very complicated question. I
23 would have to have you break that
24 down.

1 BY MR. COMBS:

2 Q. I know you don't know if
3 Prolene sutures were approved as part of
4 NDA, but I want you to assume that.

5 A. Okay.

6 Q. Now do you know whether TVT
7 is manufactured from the same material as
8 Prolene sutures?

9 A. I'm already lost. You're
10 saying that a drug, because there's a
11 drug out there, can they use that on a
12 device for a risk assessment?

13 Is that what you're asking
14 me?

15 Q. I'm asking you if --

16 A. Okay. Sorry.

17 Q. I want you to assume that
18 Prolene sutures --

19 A. Okay.

20 Q. -- were approved as a result
21 of an NDA in 1969.

22 A. Okay.

23 Q. And I want -- do you know
24 whether the mesh in TVT is made from the

1 same material as Prolene sutures?

2 A. I don't know exactly.

3 Q. I want you now to assume
4 that the mesh is made from the same
5 material as the Prolene sutures.

6 A. Okay.

7 Q. Can the fact that Prolene
8 sutures were approved as part of an NDA,
9 can Ethicon rely on that when it's
10 assessing risk --

11 MR. WALLACE: Objection to
12 form.

13 BY MR. COMBS:

14 Q. -- for Prolene mesh?

15 A. It was in my opinion, and
16 I'm going to try to explain it again.

17 When you do a risk
18 assessment for a medical device, you need
19 to look at the different inputs, such as
20 sutures and things like that.

21 But the very first step that
22 you do, and it's also in the figure in my
23 report, is that you look at the very
24 specific indications for use for that

1 device.

2 So you may use those
3 background pieces of information and
4 literature for some information, but
5 that's not what you base your risk
6 assessment on.

7 If you look at my Figure 2,
8 I believe it is, right here, the intended
9 use -- sorry -- intended purpose, you
10 have to identify those characteristics.

11 So, yes, you should look at
12 some of the other background info, but
13 that's just background information, and
14 then you make it for that specific
15 intended use.

16 Q. Okay. So as part of that
17 background information, Ethicon could
18 consider the fact that the material that
19 Prolene mesh is made from was approved as
20 a result of an NDA?

21 MR. WALLACE: Objection to
22 form.

23 THE WITNESS: I don't have
24 any idea why that would be true.

1 No. I would not say that's true.

2 BY MR. COMBS:

3 Q. So it's your opinion that
4 Ethicon can't rely on the fact that the
5 material that the mesh implant is made
6 from has been reviewed and approved by
7 the FDA.

8 A. That is not what I said
9 either.

10 MR. WALLACE: Objection to
11 form.

12 BY MR. COMBS:

13 Q. Okay. Can that be
14 considered?

15 MR. WALLACE: Objection to
16 form.

17 THE WITNESS: You're going
18 to have to please rephrase that.
19 Can what be considered?

20 BY MR. COMBS:

21 Q. Let me try again.

22 Can the fact that Prolene
23 sutures were approved by the FDA in 1969,
24 can that fact be used by Ethicon when

1 it's considering the risk of a material
2 made from the same material as Prolene
3 sutures?

4 MR. WALLACE: Objection to
5 form.

6 THE WITNESS: That was a
7 different question than you asked
8 me previously.

9 Now you are saying the whole
10 FDA rather than the drugs.

11 I think I answered the
12 question that said you should
13 consider literature, other things.

14 However, the very first
15 thing you do, and it's in my
16 report, in the start, the very
17 first block is you look at the
18 specific intended use, form
19 factors, fit, system components.

20 So you don't rely on that.

21 Of course, it can be an
22 input, but it certainly is not
23 something you rely on for your
24 risk assessment.

1 BY MR. COMBS:

2 Q. That would be one input that
3 can be considered in assessing the risk
4 of --

5 A. One of many, yes. And
6 that's specifically stated in the
7 standards, also.

8 Q. Do you know anything about
9 the regulatory history for Prolene mesh?

10 A. Anything? I know what I
11 have reviewed. I mean, I know that
12 Prolene is used in this device, and this
13 device had a CE mark. And I know that.

14 Q. Do you know whether --

15 A. So that's anything.

16 Q. Okay. Sorry. I didn't mean
17 to interrupt you. Sorry.

18 Do you know whether prior to
19 TVT being introduced to market, whether
20 Prolene mesh was sold for use as a hernia
21 mesh?

22 A. Let's go back to page 17 of
23 my report.

24 It does say that Prolene was

1 used in humans, and I know it was used in
2 sutures.

3 It could have been. I don't
4 know exactly about the hernia, but I do
5 know that the Prolene has been used as a
6 medical device.

7 And that's on 17 of my
8 report.

9 Q. Do you know what -- I'm
10 going to make sure I use the right term.

11 Have you ever used the term
12 "down-classification"?

13 A. Sure.

14 Q. What is down-classification?

15 A. Sometimes devices -- that's
16 an FDA term.

17 Sometimes devices that used
18 to be Class III or used to be Class II
19 are now classified one level lower.

20 So a II might be, say, oh,
21 okay, now we're going to call it a I. Or
22 now we're going to say, oh, it used to be
23 a III, we're now going to call it a II.

24 Q. And why is it that the FDA

1 down-classifies a device?

2 A. There could be a variety of
3 reasons. So I couldn't speak as a
4 generalization. They may feel there's
5 sufficient evidence out there now that
6 warrants it. There could be other
7 reasons, too.

8 Q. Do you know whether Prolene
9 sutures were down-classified by the FDA
10 from Class III to Class II?

11 A. You know, I don't.

12 Q. Would the fact the FDA had
13 down-classified Prolene sutures be a fact
14 that the engineers could rely on as part
15 of their assessment of risk for the TVT
16 device?

17 MR. WALLACE: Objection to
18 form.

19 THE WITNESS: I think that's
20 the same question.

21 The risk assessment for a
22 TVT device has to start with
23 looking at the TVT device.

24 There's many inputs they should be

1 looking at.

2 BY MR. COMBS:

3 Q. And that could be an input
4 that they would look at?

5 A. They could look at. But why
6 they would look at what the FDA says,
7 that's irrelevant to me.

8 I mean, they're looking at
9 the risks associated with a given device.
10 They would have to look at, you know -- I
11 guess, you know, they would have to look
12 at is it biocompatible? What are the
13 requirements for biocompatibility?

14 So they would have -- like
15 what is it is today?

16 But whether it was
17 down-classified?

18 I'm not sure how that
19 specifically would change anything with
20 risk management.

21 Q. Do you know whether Prolene
22 is biocompatible?

23 MR. WALLACE: Objection to
24 form.

1 THE WITNESS: I have only
2 read the reports that says it. It
3 said what was in reports.

4 BY MR. COMBS:

5 Q. And the reports say that
6 it's biocompatible.

7 A. The reports said they did
8 some biocompatibility testing, yes.

9 Q. Do you have any evidence at
10 all that Prolene is not biocompatible?

11 MR. WALLACE: Objection to
12 form.

13 THE WITNESS: Prolene in and
14 of itself? Or Prolene mesh? Or
15 Prolene flakes? Or Prolene in the
16 vagina?

17 I need more information.

18 Sorry.

19 BY MR. COMBS:

20 Q. Okay. Is Prolene sutures
21 biocompatible?

22 A. I didn't look at sutures,
23 per se, but I did read that the
24 biocompatibilities had been done on those

1 sutures.

2 Q. Is Prolene mesh
3 biocompatible?

4 MR. WALLACE: Objection to
5 form.

6 THE WITNESS: I would have
7 to go back and look if they relied
8 on the sutures to form the
9 biocompatibility on the mesh.

10 BY MR. COMBS:

11 Q. Do you have any information
12 at all that Prolene sutures are not
13 biocompatible?

14 MR. WALLACE: Objection to
15 form.

16 THE WITNESS: I don't have
17 information stating contrary to
18 what's in the reports.

19 I only looked in what was on
20 my list. I did not seek contrary
21 information to what was onto my
22 list.

23 BY MR. COMBS:

24 Q. Are you qualified to conduct

1 a medical assessment of whether the risks
2 of the device outweigh its benefits?

3 MR. WALLACE: I'm sorry.

4 Can you ask that one more time.

5 THE WITNESS: Am I qualified
6 to do the medical?

7 MR. WALLACE: Hang on one
8 second.

9 Do you want her to read it
10 back or --

11 MR. COMBS: Oh, I can read
12 it back -- I can ask it again.

13 BY MR. COMBS:

14 Q. Are you qualified to do a
15 medical assessment of whether the risks
16 of a device outweigh its benefits?

17 MR. WALLACE: Objection to
18 form.

19 THE WITNESS: I have
20 answered this a couple of times.

21 I am not qualified to do any
22 medical assessments. No, I'm not.

23 I'm not a physician.

24 And that's in my report

1 clearly identified.

2 BY MR. COMBS:

3 Q. In your report you say that
4 ISO 13485 has defined the requirements
5 for proper risk analysis since 1996.

6 What is your support that
7 ISO 13485 has defined the proper --
8 strike that.

9 What's your support that
10 ISO 13485 has defined the requirements
11 for proper risk analysis since 1996?

12 A. Where is that in my report?
13 I know where I got that.

14 Q. It's on page 4.

15 A. On page 4. Thanks.

16 I was hoping that we'd be
17 close to lunch.

18 MR. COMBS: Ms. Wilson, we
19 can stop any time you want.

20 Let's go off the record.

21 - - -

22 (Whereupon, a lunch recess
23 was taken from 12:04 p.m. to 1:07
24 p.m.)

1

- - -

2 BY MR. COMBS:

3 Q. Ms. Wilson, of the complaint
4 reports that are on your reliance list,
5 how many of these did you actually
6 review?

7 A. I looked at those complaint
8 reports, all of them.

9 Q. Do you remember how many
10 there were?

11 A. There was one in 2002, I
12 believe, and one was in 2006, as part of
13 the TVT-R -- no, excuse me -- as part of
14 the legacy products. I remember those
15 distinctly.

16 Q. You remember the 2002 and
17 2006 --

18 A. Yes.

19 Q. -- complaint reports?

20 A. Yes.

21 Q. Do you remember any others?

22 A. I don't remember those -- I
23 remember those specifically, and one was
24 titled a DDSA Update, but it really

1 talked about complaints.

2 Q. Do you remember any of the
3 specific complaint reports themselves?

4 A. I saw the summary reports.
5 I did see some specific complaints, yes.
6 And I cited them in my report.

7 Q. We got your report.

8 A. Okay.

9 Q. But the ones that you
10 reviewed, they would be the ones that are
11 cited in your report.

12 A. Sure. Yes, they were.

13 Q. You told us earlier that you
14 wanted to look at all the CAPAs and all
15 the risk assessments.

16 Why did you want to look at
17 all CAPAs and all the risk assessment?

18 A. You know, maybe it was
19 confusing. I wanted to look at CAPAs
20 related to any risk documents. Not all
21 the universe of CAPAs, but those related
22 to risk assessments.

23 Q. Would you have wanted to
24 look at any CAPAs that related to any of

1 the risks that you discuss in your
2 report?

3 A. Yeah. That's what I meant
4 by saying related to the risk
5 assessments.

6 I'm sorry if I was unclear.

7 Q. Well, I may be --

8 A. Any CAPAs related to those
9 risks in the report and those risk
10 assessments.

11 Q. That was the part I was
12 unsure about when you said risk
13 assessments.

14 If there was a CAPA related
15 to an underlying risk, you would have
16 wanted to see that, too.

17 A. Anything to do with that,
18 yes.

19 Q. Okay.

20 A. I mean, there may be some
21 documents that are out there somewhere
22 that I didn't cite. And if that's the
23 case, you can show them to me.

24 Q. At the beginning of the

1 deposition, I asked you a question about
2 an audit, and you were real careful to
3 say to me, Hey, what I did was not an
4 audit.

5 So here's what I want to ask
6 you: If you had done an audit, what
7 additional things would you have done?

8 A. I'm not sure that there
9 would have just been additional, they
10 would have also been different.

11 Q. Okay.

12 A. Audits are very specific.
13 You go in and look to a specific
14 standard. You look at that standard.
15 Then you take a statistically, or if at
16 all possibly, you take a statistically
17 valid sample size.

18 For example, when I audit, I
19 use a C equals 0 sampling plan with an
20 AQL of 2.5 to do my audits. And I get
21 evidence based on a specific number of
22 incidents.

23 Say, for example, they had
24 20 CAPAs, then I would probably look at

1 five records based on that sampling plan.

2 Then I would look at each.

3 So I would look at the evidence based on
4 a very systematic methodology and only
5 cite maximums as to those standards. You
6 can sometimes say they're major or minor
7 non-conformances, and then you can have
8 opportunities for improvement.

9 So that's -- again, it's a
10 snapshot in time, and you can't see all
11 the evidence.

12 Q. Okay. And so what is it
13 that you did in this project that was
14 different than that?

15 A. Well, in this project, not
16 only did I look -- you know, keep my
17 auditing hat on, but I also looked at all
18 of my experience from industry. I looked
19 at my experience from, you know, GLPs.

20 I looked at my experience as
21 quality engineer. I have been certified
22 as quality engineer for, I can't
23 remember, since probably the '80s, 1980s.

24 I looked at my science

1 background. I looked at Class I, II, and
2 III devices.

3 You know, so I looked at a
4 whole bunch of evidence and data, and as
5 well as the standards.

6 So I didn't just use a
7 standard, a specific point in time. I
8 looked at my overall experience.

9 And, you know, I've had a
10 lot of clients in a lot of industries.

11 And so I'm really fortunate
12 that I've been able to look at everything
13 from slaughterhouses -- I did
14 slaughterhouse audits -- through, you
15 know, switchboard manufacturers.

16 So I've really had the
17 chance to bring a lot of different
18 backgrounds to this report.

19 Q. Have you done audits
20 pursuant to ISO 13485?

21 A. Many, many.

22 Q. For what types of products?

23 A. Oh, my goodness. I just
24 have a whole audit list I have to keep to

1 keep my certifications.

2 I have done it for all kinds
3 of different medical devices, for their
4 suppliers. I do a lot of supply chain
5 audits.

6 And as part of that, we do
7 look at the design history documents.
8 But we just, again, look at a point in
9 time. We take a sample.

10 And I don't look at the
11 whole preponderance of evidence. That's
12 in my whole background.

13 Q. Earlier, I asked you
14 questions about the audits that the
15 notified body conducted of Medscand and
16 then Ethicon in the late 1990s and 2000.

17 And you told me that you
18 didn't know what had been reviewed during
19 those audits.

20 Now, does the EU Directive
21 establish what is to be reviewed during
22 those audits?

23 A. You know, I do remember
24 looking at those as part of the technical

1 file. I mean, I do remember looking at
2 those certifications.

3 And each different notified
4 body comes in with their own checklist
5 and basically calls out what they're
6 looking for.

7 And they -- I don't know if
8 each notified body is exactly the same,
9 but they are becoming more similar over
10 time.

11 Q. And those are done pursuant
12 to Council Directive 93/42/EEC, aren't
13 they?

14 A. They're supposed to all be
15 done in accordance.

16 The notified bodies are
17 supposed to be trained to that. But I do
18 know there's a huge variation between
19 notified bodies.

20 MR. COMBS: This is 8.

21 - - -

22 (Whereupon, Exhibit Wilson 8
23 was marked for identification.)

24 - - -

1 BY MR. COMBS:

2 Q. Ms. Wilson, I have handed
3 you what has been marked Exhibit 8, and
4 it's the Council Directive 93/42/EEC of
5 June 14, 1993 concerning medical devices?

6 A. This is as amended? This is
7 the most recent one as amended?

8 Q. You tell me.

9 A. I would have to read through
10 it all. That's why I asked.

11 Q. Okay.

12 A. So --

13 MR. WALLACE: This is like
14 double-sided 20 pages.

15 Do you really want her to
16 read through it?

17 BY MR. COMBS:

18 Q. Well, the questions that I'm
19 going to ask you about it are at
20 Sections 3.2 down through 4.

21 A. Not these articles?

22 MR. DAVIS: Annex II.

23 THE WITNESS: Can you tell
24 me what pages?

1 So there's the articles.

2 MR. DAVIS: It's Annex II.

3 BY MR. COMBS:

4 Q. So in Annex II.

5 A. Okay.

6 Q. Paul has corrected me. And
7 the pages aren't numbered, but it's
8 about -- you know, about halfway through.

9 A. I see it.

10 Q. Have you found it? Did you
11 find 3.2?

12 A. Not yet.

13 Q. It's on the next page.

14 A. Okay. Let me just start
15 with this section, Annex II.

16 Q. Sure.

17 A. (Witness reviewing
18 document.)

19 3.2 through what?

20 Q. Well, let's start with
21 Section 3.3.

22 A. Okay. I'm just starting at
23 3.2.

24 (Witness reviewing

1 document.)

2 Okay. I read through 3.3.

3 Q. And it's Section 3.3, does
4 it require the notified body to audit the
5 quality system to determine whether it
6 meets the requirements referred to in
7 Section 3.2?

8 A. Just so I'm clear on this,
9 and we don't get into another round of
10 what we did on this one, are you just
11 asking me to re-read what you're asking,
12 what's written here, to confirm
13 what's written here?

14 Q. You're here as an expert in
15 the field.

16 A. But that's what I asked --
17 that's what you just asked me, I believe,
18 so that's why I'm asking for
19 clarification.

20 Q. Well, let's start with this.
21 Is that what it says?

22 MR. WALLACE: I don't think
23 you need to be an expert to be
24 able to read, but you can read

1 what it says.

2 THE WITNESS: That's why I
3 was asking for clarification.

4 BY MR. COMBS:

5 Q. Here's 3.3. Does it say,
6 The notified body must audit the quality
7 system to determine whether it meets the
8 requirements referred to in Section 3.2?

9 Is that what it says?

10 A. It does say that, yes.

11 Q. You have done a hundred-plus
12 audits.

13 Do you know whether under
14 the EU Directive, whether that is
15 something the notified body auditor must
16 do?

17 A. I need to be clear. I do
18 quality management system audits or
19 inspections. I don't do inspections, I
20 do audits on behalf of my clients. I'm
21 not a regulator.

22 And, of course, I know that
23 they do inspections, because I'm
24 certified. And I believe I did state

1 that before, that they come in and they
2 do inspections.

3 Q. Okay. And is one of the
4 things they inspect, the design
5 specifications including the standards
6 which will be applied and the results of
7 the risk analysis?

8 A. It depends on the scope of
9 your assessment.

10 So in my case, for example,
11 we don't do design. We exclude
12 Section 7.3 of ISO 13485. So in that
13 case they wouldn't, in other cases they
14 would.

15 Sometimes they would check
16 different things. And also depends if
17 it's a full quality system audit or a
18 surveillance audit.

19 That's why asked. I didn't
20 know on one of these certificates if it
21 was because it was a full quality system
22 or if it was a surveillance audit
23 follow-up.

24 Q. And right on the front, it

1 says, Full Quality Assurance System.

2 A. That's true. However,
3 sometimes they come in and they do a full
4 system -- they will still say the same on
5 the front, but they do what's called
6 surveillance audits where they don't look
7 at everything. They do a full audit and
8 then they come back like every second
9 year. In our case, the next year they do
10 a surveillance audit.

11 So they wouldn't -- the
12 certificate would still say the same, but
13 they wouldn't actually look at all the
14 sections.

15 Q. And you don't have any
16 information at all as to whether this was
17 a full audit or a surveillance audit, do
18 you?

19 A. I would have to look at the
20 history of all of these certifications.

21 Like this one says -- when
22 you say "any at all," I'm sure I could
23 try to put all of these side by side for
24 the history of the product and try to

1 figure that out for you.

2 Q. And that's not something
3 that you've done.

4 A. No, I haven't. I just
5 looked at the ones that I have listed in
6 my report and the ones yesterday.

7 I was looking at
8 Ms. Duncan's report and there was a
9 different --

10 - - -

11 (Brief interruption.)

12 - - -

13 THE WITNESS: Sorry. I lost
14 track with that interruption.

15 Refresh me. Go ahead.

16 BY MR. COMBS:

17 Q. Certificate indicates it's a
18 whole quality systems assurance audit,
19 doesn't it?

20 A. Yes. And they will, whether
21 it's a surveillance or not.

22 Q. And do you have any
23 information at all that the audits that
24 are reflected on Exhibit 6 and 7 were not

1 full quality assurance system audits?

2 A. I would not have that
3 information at the present. I don't know
4 if it was surveillance or not.

5 Q. In order for the CE mark to
6 be issued --

7 A. Mm-hmm.

8 Q. -- does a full audit have to
9 have been conducted?

10 A. It has to have been
11 conducted.

12 Q. At some point, in order to
13 get CE mark.

14 A. Right. It's generally every
15 third year. So they do a full and then a
16 surveillance. At least that's how mine
17 does it, and then -- surveillance, and
18 then a full.

19 But there may be things that
20 are later in here that you have to go and
21 do another full in between, depending on
22 situations.

23 Q. But you have to have a full
24 before the product is marketed, don't

1 you?

2 A. Before what product is
3 marketed?

4 So if you have a full and
5 say you have a line extension, you can
6 also notify and not have to have an
7 additional one.

8 So it's not as
9 straightforward as you're saying.

10 Q. Before TVT was marketed
11 pursuant to the CE mark, there had to
12 have been a full audit of TVT, wasn't
13 there?

14 A. There had to be a notified
15 body audit of Medscand where they looked
16 at some TVT documents.

17 Q. And the full audit would
18 cover design control, wouldn't it?

19 A. If that's in the scope, yes.

20 Q. And, the full audit, the EU
21 Directive discusses design control,
22 doesn't it?

23 A. Could you point to me where
24 you're looking?

1 Q. Well, right here, in C,
2 Design specifications, including
3 standards which will be applied and the
4 results of the risk analysis, and also a
5 description of solutions adopted to
6 fulfill the essential requirements...

7 A. I see this right there.

8 Q. Techniques used to control
9 and verify the design?

10 A. Right. So in their audit,
11 they would take a sample at a point in
12 time, and they would look at a document
13 or two, depends on your notified body, to
14 look at the extent, at what product you
15 samples.

16 Q. And that would include
17 design control, wouldn't it?

18 A. Let's look here.

19 It says, Design control
20 here, and it says, Design control here.

21 To the best of my knowledge
22 it would include it. I have no documents
23 beyond that to state that it wouldn't or
24 would.

1 Q. And just so the record is
2 clear, when you say, it says, Design
3 control, you were pointing to --

4 A. It says, Design, it doesn't
5 Design control.

6 Q. And you you were pointing to
7 Exhibit 6, and then you were pointing to
8 Exhibit 8 when you said, Design control.

9 A. 3.2 (c).

10 Q. Ms. Wilson, I asked this
11 question right before we went on the
12 break, so if you answered it and I just
13 didn't catch the answer, I'm certainly
14 not trying to badger you with this.

15 I think what I asked you
16 right before we took the break was
17 whether ISO 13485 was ever recognized by
18 the FDA prior to 2003.

19 A. That's not at all what I
20 recall you asking me, but we can try that
21 question.

22 Q. Whether I asked it, but
23 let's just ignore whether it was asked
24 before or not, let's just start off.

1 Like right now, does the FDA
2 require a medical device manufacturer to
3 comply with ISO 13485?

4 MR. WALLACE: Object to
5 form.

6 THE WITNESS: They -- that's
7 apples and oranges. That isn't
8 peaches and cream.

9 BY MR. COMBS:

10 Q. Okay.

11 A. The FDA has FDA stuff. EU,
12 Canada, many other countries accept
13 13485. So that question doesn't make any
14 sense to me.

15 Q. So I'll try it again.
16 Here's the question.

17 Does the FDA require
18 compliance to ISO 13485?

19 A. For products distributed
20 within the U.S. by U.S. medical -- no,
21 they do not.

22 They do have harmonized risk
23 procedures to ISO 14971, however.

24 Q. Is there an FDA reg that

1 required Ethicon to have conducted risk
2 analysis of TVT at the time TVT was
3 manufactured by Medscand, not Ethicon?

4 A. Could you break that up.

5 Q. Is there an FDA reg that
6 requires Ethicon to have conducted risk
7 analysis of the product, of TVT, at the
8 time it was manufactured by Medscand?

9 A. I'm going to go back. My
10 report, I exclusively -- I did not look
11 at FDA because that was outside of the
12 scope of my report.

13 So I just want to make sure
14 that you're aware of that.

15 There's always been
16 standards that medical devices -- are
17 incumbent upon them to have safe medical
18 devices. And that clearly says that.

19 It doesn't matter what
20 country you're in, it's ethical and
21 right.

22 And so your question was,
23 does the FDA have regulations that
24 required --

1 Q. That required --

2 A. -- Medscand; right?

3 Q. No, ma'am.

4 A. Okay.

5 Q. It was: Are there FDA
6 regulations that required Ethicon to have
7 conducted risk analysis of the product at
8 the time it was manufactured by Medscand?

9 MR. WALLACE: Same
10 objection.

11 THE WITNESS: There are FDA
12 harmonized standards that are
13 incumbent upon U.S. manufacturers
14 to follow.

15 So 14971, which is pursuant
16 to risk analysis.

17 So you would need to have --
18 and we talked about risk analysis.
19 So, yes, they had to follow risk
20 analysis, risk management,
21 depending on -- Medscand, it was
22 risk analysis.

23 BY MR. COMBS:

24 Q. Yes, but I apologize, that

1 wasn't the question I asked.

2 The question I asked was --

3 A. I'm trying very hard to
4 answer you.

5 Q. Listen, I'll just try it
6 again.

7 The question I was asking
8 is: At the time that Medscand was the
9 manufacturer of the product, not Ethicon,
10 so prior to the third quarter of 2000, is
11 there a reg that requires Ethicon to have
12 conducted risk analysis during the time
13 that the TVT is being manufactured by
14 Medscand?

15 A. What the requirement was is
16 for that Ethicon have supply chain
17 controls.

18 And in supply chain
19 controls, you certainly have -- which is,
20 you know, under Section 7. -- you know,
21 it doesn't matter what section.

22 They had to have control of
23 their suppliers. That's what Ethicon had
24 to do.

1 And as part of that, it was
2 incumbent upon them to look at their
3 suppliers and ensure that they did have
4 the right systems in place to have a safe
5 device.

6 Q. Did Ethicon have to do a
7 risk analysis prior to the time it
8 assumed the manufacture of the product?

9 A. Ethicon, independent of
10 their supplier standards?

11 Q. Yes, ma'am.

12 A. That makes no sense. If
13 they didn't -- if they weren't the
14 manufacturer, but they were under some
15 kind of agreement and they were supplying
16 product, like Medscand was supplying
17 product to Medscand -- sorry,
18 backwards -- Medscand was applying to
19 Ethicon, they were working together, then
20 Ethicon had to have supplier controls.
21 And as part of that, they would look at
22 the safety.

23 Q. And when you're referring to
24 the supplier controls, what standard are

1 you referring to?

2 A. Supply chain controls,
3 they're right in there, they have been in
4 every quality system regulation since --
5 at least since 1963.

6 Q. And do those supply chain
7 controls require Ethicon to perform --

8 - - -

9 (Brief interruption.)

10 - - -

11 BY MR. COMBS:

12 Q. Now, is there any
13 requirement that Ethicon have conducted
14 risk analysis of the product at the time
15 it was manufactured by Medscand?

16 A. I need some clarification
17 about were they in a supply chain
18 agreement?

19 Was this during a license?

20 Or was this just when
21 Medscand was supplying it on their own?

22 I'm not sure of the
23 circumstances around which you're asking.

24 Q. Do you know what the

1 arrangement was between Ethicon and
2 Medscand?

3 A. I know that they had some
4 kind of an agreement between 1997 and
5 1999. I believe it was about 26 months
6 they had an agreement prior to the
7 purchase by Ethicon -- of Medscand by
8 Ethicon.

9 Q. Okay. During that 26-month
10 period, was Ethicon required to do a risk
11 analysis?

12 A. I have not read that
13 agreement.

14 Generally, in those
15 agreements, those quality agreements,
16 they specifically delineate what the
17 requirements are.

18 So if you have that
19 agreement, I'd be glad to take a look at
20 it.

21 Q. As we sit here today, you
22 haven't read it.

23 A. I have not looked at the
24 agreement between Ethicon and Medscand to

1 see who took exact requirements for what
2 portion of the different systems.

3 Q. And as we sit here today,
4 you don't know whether Ethicon was
5 required to do the risk analysis under
6 that agreement.

7 A. I have not read that
8 agreement, so I cannot say, no.

9 I do write those supplier
10 agreements and do know they vary.

11 Q. Has the FDA issued
12 performance standards for surgical mesh?

13 A. Performance standards?

14 Q. Yes, ma'am.

15 A. You know, I really didn't
16 look at the FDA and what the requirements
17 were or any of those documents.

18 Q. Do you know?

19 A. I don't know. I looked --
20 really focused on my area of expertise.

21 Q. What regulations were
22 applicable to Medscand at the time TVT
23 was first brought to market?

24 That wasn't a very good

1 question.

2 A. What year was that? Tell me
3 a little more.

4 Q. I believe it was in 1997.

5 In 1997, what requirements
6 were applicable to Medscand?

7 A. Okay. 1997 -- I would
8 probably go to my time line. We have a
9 beautiful clean time line in here.

10 And I also have a cheat
11 sheet, because these things changed over
12 time. And on here -- and I also
13 footnoted that not all standards are on
14 here.

15 So most of them are very
16 similar over a given point in time.

17 1997. So I guess now I need
18 to know what exact day and month before I
19 could answer your question.

20 I mean, in October -- I
21 mean, the date of -- I mean, that's
22 how -- most of them are so stinking
23 similar, but it really doesn't matter,
24 because they're ISO 9001 with a 1345, an

1 EN 1441, which was very, very similar to
2 the 46000 ones.

3 So February, the date of
4 publication --

5 Q. October 1997.

6 A. October 1997.

7 So 22nd of October 1997 --
8 all right. Let me dig through here,
9 because there's also cut-in dates.

10 So in one of those binders
11 there's the DAV and the DO, so I have
12 like the 46001.

13 So now you're looking for
14 the quality system and the risk, both?

15 Q. What ISO regs would have
16 been applicable to Medscand in October of
17 1997?

18 A. So the full month of
19 October.

20 New standards come out.
21 Look-it, honestly, I'm not being a joke,
22 like the 22nd of October, a new one came
23 out.

24 Q. The date at issue on the EC

1 certificate is October 2nd, 1997.

2 A. Okay.

3 Q. So on October 2nd, 1997.

4 A. Well, if that's the case,
5 then we have -- right here, we have
6 ISO 9001 is applicable. And then we have
7 to look at the cut-in date.

8 So when these standards were
9 published, that's the DAV. And the
10 EN 46001, and...

11 Q. And --

12 A. I mean it says right there.

13 Q. Yeah.

14 A. But if you want me to go
15 look at it here.

16 Q. No, no.

17 A. ISO 9001. Look-it, I got
18 them both.

19 Q. Yeah.

20 So the standards that would
21 have been applicable to Medscand as of
22 October 2nd, 1997, the ISO standards --

23 A. Right.

24 Q. -- would have been

1 9001:1994, and EN ISO 46001:1996.

2 A. And that's exactly what I
3 just pulled out.

4 Q. Okay.

5 A. And I have got them in these
6 piles.

7 And it gets even trickier,
8 because there's date of availabilities,
9 there's date of, you know, announcements,
10 date of publications. That's why I
11 wanted to check.

12 Q. Are EN 1441 and ISO 46001,
13 are they similar?

14 A. No. 46001 and 1441,
15 they're --

16 Q. Yeah. EN ISO 9001 and EN
17 ISO 46001 --

18 A. No. This is actually a
19 predecessor of the 1345. Because this
20 is -- these aren't standalone yet.

21 Q. Okay. Thank you.

22 Ms. Wilson, the certificate
23 for -- the 1998 certificate has the same
24 standards, EN ISO 9001:1994 and EN ISO

1 46001:1996, would you agree that those
2 were the standards applicable to Medscand
3 as of --

4 A. Isn't that the same
5 certificate? I'm sorry.

6 Q. No, ma'am. The first one --

7 A. Can I take a look?

8 Q. All right. So here's the
9 question I have then.

10 For the revision date of
11 September 23rd, 1999, would the same
12 standards have been applicable to
13 Medscand at that time?

14 A. I'll take a look. 1999 --

15 Q. Yes, ma'am. September 23,
16 1999.

17 A. Do they say which version of
18 the 46001? Because -- I'm sorry. I
19 didn't mean to take it from your hand. I
20 was just starting to look at the exhibit.

21 Because there is an EN 46001
22 that changed dates, but it's the same
23 standard.

24 And they're -- so in 1999,

1 they had to come out with the 1345 had
2 come out, but it was probably in one of
3 those transition periods.

4 So it was in those
5 transition periods. So you have to go
6 back and say that in 1999, yes, it was
7 46001 and 9001.

8 Q. And the certificate that we
9 marked as Exhibit 7, which is dated
10 March 7, 2000, it's got the same
11 standards.

12 A. Right.

13 Q. And so would those have been
14 the same standards that would have been
15 applicable at that time as well?

16 A. Now, I just want to mention
17 that, you know, I have seen those
18 certificates, and I have seen those by
19 many companies.

20 And because you have those
21 certificates, that's a great thing. But
22 that doesn't mean that their quality
23 system is deployed very -- it doesn't
24 guarantee you of a well-deployed system.

1 Q. And the question I'm just
2 asking is that on March 7 of 2000, those
3 would still have been the standards in
4 place.

5 A. Last you asked me, 1999.
6 I'm sorry.

7 MR. WALLACE: Let me object.
8 Were you finished with your
9 answer?

10 MR. COMBS: I didn't mean to
11 interrupt you. If you weren't, I
12 apologize.

13 THE WITNESS: I totally lost
14 my train of thought.

15 MR. WALLACE: Okay. Let me
16 just -- excuse me for one minute
17 just to say something.

18 If you're not finished with
19 your answer, just -- he
20 understands. Put up your hand or
21 something and go ahead and finish.

22 BY MR. COMBS:

23 Q. And I'll try not to
24 interrupt you. I certainly wouldn't do

1 it on purpose.

2 A. Okay. I was just trying to
3 get the point across that I have seen
4 those at many places and I have audited
5 many places.

6 And because you have those
7 standards in and of themselves, and these
8 are regulators, they know the dates.

9 I'm looking them up, because
10 these regulators are -- and this is not
11 easy, because you have to go back to CEN
12 and CENELEC, and look at each exact date
13 of a publication date, and I have done
14 that on many of these.

15 And then you have to know,
16 sometimes country-specific things.

17 So the regulators, I'm sure
18 they would know.

19 And yes, I'm confirming to
20 the best of my ability. But I'm not a
21 regulator. I'm a consultant and I go
22 into places. And I have seen
23 certificates. In fact, I saw a
24 certificate.

1 And guess what? It was
2 issued on a day that happened to be an
3 ice storm day and production wasn't even
4 running.

5 So I think this is great,
6 but it doesn't necessarily mean that
7 everything was hunky-dory.

8 Q. And for the time periods in
9 question, between September 1997 and
10 March of 2000, the standards that would
11 have been in place for TVT would have
12 been -- in Europe would have been
13 EN 46001:1996 and ISO 9001:1994.

14 A. Well, now I have go look
15 between '99 and 2000, because I don't
16 think that was covered on the
17 certificate.

18 This one said '99; correct?
19 And then you moved it to 2000?

20 Maybe --

21 Q. Let's take a step back here
22 for a second.

23 A. Please.

24 Q. Because I'm not trying to

1 make this --

2 A. Because you keep switching
3 here.

4 Q. I'm not trying to make this
5 any more complicated.

6 The first certificate has
7 got ISO 9001:1994.

8 A. And we already established
9 that.

10 Q. And the second certificate
11 has got the same standards for a later
12 time period.

13 A. Do they have -- what I'm
14 trying to get at is do they have the
15 exact same '94, '96, fine. I think we
16 have already established that.

17 Right. I had confirmed that
18 I believe that to be true.

19 Q. All right.

20 A. But the regulators do know
21 best. That's their job.

22 Q. You mentioned CEN. I just
23 want to make sure the record is correct.

24 What is CEN?

1 A. I believe you mention CEN.

2 Q. Okay. All right. I
3 mentioned, it whatever.

4 What is CEN?

5 A. The technical board that
6 approves -- there's CEN and CENELEC.

7 It's a European -- I would
8 have to go look it up. It's like a
9 Central European Commission. It's part
10 of the regulators in the EU.

11 And I'm not an expert
12 regulator. I'm an expert in quality
13 systems, risk management across all
14 different kinds of medical devices.

15 Q. And what does CEN approve?

16 A. CEN, to my knowledge,
17 carries out the -- or execute the
18 regulations by the European Commission.

19 Q. Thank you.

20 Ms. Wilson, on your reliance
21 list there were no risk assessments for
22 Prolene sutures.

23 You didn't review any risk
24 assessments for Prolene sutures, did you?

1 A. No. I was looking at mesh
2 for the TVT-R only and mechanical cut
3 only.

4 Q. There were no risk
5 assessments for Prolene hernia mesh on
6 your reliance list, were there?

7 A. No. Same answer as
8 previous.

9 Q. In your report, you mention
10 Preventia -- well, strike that.

11 What is the Preventia in
12 this case?

13 A. There's an application FMEA.
14 There was a Revision 7 in the document
15 called Design History and also called
16 Fact Book. And that was also in the
17 technical file that I looked at.

18 So it was in multiple spots
19 under different Bates numbers.

20 And, in fact, that was the
21 only thing that I found early on in the
22 design phase.

23 So that was an application
24 FMEA, which looked at during implant what

1 could happen.

2 Q. Were any aspects of the
3 design looked at in the Preventia?

4 A. Well, there were eight
5 revisions. And all I looked at was
6 Number 8. Actually, I did have a seven,
7 although there was a footnote that
8 said -- there wasn't a seven.

9 I focused on Number 8. And
10 there were aspects of how the design was
11 put into use. So with respect to the
12 user emplacement and the application,
13 that was in there.

14 But traditionally what's
15 done, and what I did at the exact same --
16 you know, the same time frame as we would
17 go and we would look at the questions and
18 the standards and say, How does this
19 device fit with this device function?

20 Even if it was like a
21 different version of a shoulder. And one
22 shoulder is not the same as another
23 shoulder, because it might be installed
24 differently.

1 Then we would look at each
2 and every -- so we would at the overlook
3 view as a system, then you look at the
4 component level, and look at each and
5 every component and what -- for each
6 function what could go wrong.

7 And I did not see that on
8 the design.

9 That would be -- and I have
10 that in my report as the different types
11 of FMEA. All we saw was the application
12 and the Preventia Report Rev. 8.

13 Q. And in your report you say
14 that Ethicon does not have previous
15 versions of the risk assessment,
16 including Revisions 1 through 7.

17 And did I understand you
18 just made a correction that you did have
19 7?

20 A. No. What I have quoted is
21 what an expert said in his report, that
22 the 1 through 7 -- I think I have that
23 footnoted -- that that was nowhere in
24 Ethicon.

1 But I somehow ended up with
2 a Version 7. So I think my footnote is
3 what said the 1 through 7 is not there.
4 And then I ended up locating like just
5 yesterday a Version 7. So...

6 Q. So here's what it says,
7 Ethicon does not have the previous
8 versions of the risk assessments,
9 including Revisions 1 through 7, which
10 would include the version of the risk
11 assessment performed prior to the launch
12 of TVT-R in 1998.

13 Now, that is not correct, is
14 it?

15 A. Where are you at?

16 Q. I'm on page 15 of your
17 report.

18 A. Right. There's an expert
19 footnote that says there is no 1 through
20 7. I think it's footnoted somewhere. I
21 know it's footnoted in here.

22 Q. Yeah. Footnote 67 is what I
23 think you're referring to.

24 A. So there is no 1 through 7.

1 This is an application only.
2 Like I said, it doesn't have a design.
3 It's just looking at the installation for
4 how you put it in a body under a surgical
5 technique.

6 So it's not what I just
7 described. And low and behold a
8 Version 7 did show up, like after I wrote
9 this. And I was just trying to be
10 forthright.

11 Q. I appreciate it.

12 But the statement that
13 Ethicon doesn't have the Versions 1
14 through 7, that's not correct.

15 A. To the best of my knowledge,
16 they don't have 1 through 6 now. I have
17 never seen those.

18 And the other expert that
19 was in charge of the corporate designee
20 said that he had never seen 1 through 7.

21 So I'm just honest and said
22 I saw 7. So I have never seen 1 through
23 6.

24 Q. And did you ask the lawyers

1 that retained you in the case to provide
2 you with other copies of the Preventia?

3 A. I don't know how many times
4 I need to say this. I'll try again.

5 I asked them to provide me
6 anything related to risk, whether it's
7 risk anything. So related to TVT
8 mechanically cut, TVT-R mechanically cut
9 mesh, anything in this great big bucket
10 called risk I asked for.

11 Q. And earlier versions of
12 Preventia, one of the things you
13 wanted --

14 A. Anything. And I got the
15 expert report that said there was no 1
16 through 7 -- 1 through 7, so they relied
17 on 8.

18 And then I recently, since I
19 submitted this report, came into
20 Version 7, and was just trying to be --

21 Q. But --

22 A. -- honest.

23 Q. I'm sorry I interrupted you
24 again.

1 Were you finished?

2 A. Yeah.

3 Q. And as we sit here today,
4 you have never seen Revision 5.

5 A. No, not to my knowledge.

6 Q. Was there a requirement that
7 a dFMEA be performed by Medscand in 1997?

8 A. Yes.

9 Q. What is that standard?

10 A. Well, there's EN 1441. And
11 that talks about in the design --
12 actually, I have it right here. May I
13 look at it and show it to you?

14 Q. Of course.

15 A. But the requirement is that
16 you analyze risk during the design, and
17 you can do it in a variety of ways. You
18 can use different tools to accomplish the
19 same tasks.

20 So you could use -- and I
21 listed some of these earlier this
22 morning. You could use a HAZOP. You can
23 use a hazard analysis. You can do a
24 fault tree analysis. But you still have

1 to analyze your risks during the design.

2 And then as things change,
3 you have to go back and re-evaluate that.

4 So, you know, the question
5 was: Does it have to be exactly a dFMEA?
6 Well, it has to accomplish that function.
7 And you could use a slightly different
8 tool.

9 And that's what the standard
10 says, that you have to look at safety,
11 including the acceptability of risk for
12 the medical device. You have to look at
13 the benefits of the device and the risks
14 associated with the procedure, the
15 control of the risks.

16 It talks about the risk
17 analysis. And it says right here, It
18 shall be followed and it shall be
19 documented.

20 You could look at all a list
21 of possible hazards as identified.

22 And so it's pretty -- and
23 it's got a picture in it. It gives you
24 questions.

1 So it's pretty -- and it
2 does go back and talk about, you know,
3 review of the risk, and then it gives you
4 some other guidance in the back.

5 Q. So pursuant to 1441, the key
6 is that the risk be analyzed, not that it
7 be titled dFMEA.

8 A. Right. And it talks in
9 Annex D about the different things. The
10 procedures within Ethicon talked about
11 using for risks and safety analysis, they
12 called it a DSA and a FMEA, then later
13 they called it a dFMEA, I believe, and
14 aFMEA.

15 So those are the terms, and
16 they term it a dFMEA. I have it in my
17 report. And it's right in that Stamatis
18 book, which is -- I use all kinds for
19 training different medical devices.

20 If you look at Figure 7, and
21 that talks about, you know, system
22 levels, design, and it sort of calls out
23 the whole dFMEA, pFMEAs, things like
24 that.

1 But it is acknowledged that
2 you could use a HAZOP type of format to
3 accomplish the same task.

4 Q. The key thing is just that
5 the risks are analyzed.

6 A. Well, and that they are
7 specifically analyzed. They're
8 evaluated, that the hazards are
9 identified.

10 Then you look at the
11 probability of those hazards and the
12 severity of those hazards. And that's
13 how you identified the risks.

14 And then you have to look
15 at -- you know, take different things
16 into account, and look at -- most call it
17 the risk priority number, which basically
18 tells you how important those things are.

19 And that you look at it in
20 the design phase. And that's the key,
21 because if the design phase isn't done
22 right, you don't know what to mitigate,
23 how to mitigate it.

24 Because it's right here. I

1 mean, you can mitigate in some ways.

2 Q. And did any standard require
3 a dFMEA to be done at any point?

4 A. No standard is going to
5 require a specific tool be used. I
6 believe I said that most commonly in my
7 report, and right here the most common
8 one is FMEA.

9 And, yes, it does say
10 design. So it does say you need to do a
11 design risk analysis.

12 Q. So design risk analysis,
13 yes. Design FMEA specifically, no.

14 A. No. That's the most common
15 tool, as I cited, and it's the first tool
16 that's required -- that is defined in
17 here.

18 MR. DAVIS: "Here" is 1441?

19 THE WITNESS: Yes.

20 BY MR. COMBS:

21 Q. What is it about the
22 Preventia Revision 8 that makes it not an
23 analysis of the design risk?

24 A. Let me go back and try to

1 explain a little different way.

2 So what they did is they
3 went down -- go look back at this figure
4 in my report.

5 So they went down here.
6 After the system concept was developed,
7 after the device was through its design,
8 after the process had been established
9 and said, let's see how it works in the
10 user's hands.

11 So these, I never saw any
12 risk analysis of those phases. I saw the
13 downstream application risk analysis,
14 which doesn't say, like I tried to
15 explain -- let me try again.

16 You look at the system
17 overall and how, say, the instruments or
18 accessories would interact with the
19 device, how the different components of
20 the devices could interact, and then you
21 break down each component in detail
22 during the initial device phases, then
23 you go reanalyze it as you progress
24 through the design prior to launch.

1 And so you would say, okay,
2 so this component has three -- these
3 three functions. It has to -- for
4 example, it has to be -- the needle has
5 to be sharp. It has to be at a certain
6 angle. It has to fit with the guide.

7 So those functions would
8 each then be analyzed for many different
9 things and a severity -- they're not a
10 one-to-one, they're one to many.

11 So then you would have to
12 look at each and every combination,
13 assess the, okay, what's the hazard?
14 What's the potential severity? What's
15 the frequency? What's the RPN? What's
16 the mitigation? What's the RPN after
17 mitigation.

18 Q. And so the critique that you
19 have of Preventia Revision 8 is it
20 doesn't assess the risk of the device
21 itself, it's the application and use of
22 the device?

23 A. That's not quite what I
24 said.

1 Q. Okay.

2 A. Let me try to clarify.

3 I said it doesn't include
4 the design portion of it. So, yeah, the
5 design is part of the device, but there's
6 other things in the design that you could
7 mitigate through.

8 So you look at the design,
9 absolutely. You look at the device
10 itself. But in part of the design, you
11 look at the interaction between the
12 device and the rest of the system.

13 So it's not just the device,
14 it's the system also.

15 Q. And what parts of the design
16 needed to be included in the risk
17 analysis that aren't in the Preventia?

18 A. Every single component.

19 Let me restate that.

20 I have tried twice. I'm not
21 sure how I can restate it.

22 You look at the system
23 level, which is here.

24 MR. WALLACE: And just to be

1 clear, you also pointed to this
2 earlier.

3 You're referring to a figure
4 on page 7 and you're circling some
5 boxes.

6 So just to be clear for the
7 court reporter, if you could refer
8 to --

9 THE WITNESS: Oh,
10 absolutely.

11 BY MR. COMBS:

12 Q. And so you are referring to
13 Figure 4 in your report on page 7?

14 A. Right. It comes from this
15 book right here, my favorite, Failure
16 Mode and Effect Analysis, Stamatis book.

17 Q. And so is the problem with
18 the Preventia risk analysis, that it
19 doesn't address the components?

20 A. The problem with the
21 Preventia is, it doesn't do -- it's after
22 the fact, and it doesn't address the
23 systems. It doesn't address the
24 interaction of the system with the

1 components.

2 It doesn't address
3 different -- there are many things called
4 out in the EN 1441 and the subsequent
5 standards that you have to look at.

6 It says, okay, does it talk
7 about the toxicity, the endotoxin? Does
8 it look at the -- let's just look at some
9 of those things.

10 I mean, they're very
11 specific.

12 Q. All right. And just so the
13 record is clear, I want to make sure that
14 what you're looking at right now, it's
15 EN 1441?

16 A. Correct.

17 Q. Thank you.

18 A. Right. These are just some
19 examples.

20 Q. All right. And these are
21 things that need to be covered in the
22 design risk analysis.

23 A. Right. So when you look at
24 the design, and these are early, again,

1 in the design phase. You want to make
2 sure that your system and concepts are
3 good to start with, so you don't get all
4 the way down the road and come up with
5 something that, oh, my goodness, this
6 isn't what we thought was going to be.
7 Right?

8 So you want to say, okay,
9 does this look -- here's just an example
10 of estimation of the risk.

11 Does a hazard occur in the
12 absence of a failure? Does a hazard
13 occur in a failure mode only? Is there
14 multiple failure conditions? Can it be
15 detected by the user of the head of it?

16 You look at the types of,
17 for example, of different hazards with
18 homogeneity. You look at hazards of the
19 process, manufacturing process -- well,
20 that's not design, that's in the process.
21 I never saw process of FMEA either.

22 I'm sorry.

23 Q. All right. And so for TVT,
24 for example, would you need to look at

1 characteristics of the mesh?

2 A. You would need to look at
3 characteristics of the mesh. You would
4 look at the needle, the packaging. You
5 would look at -- it says, incorrect
6 formulation, mechanical forces, moving
7 part, suspended masses, vibration.

8 How about, you know,
9 inadequate specification of accessories.

10 And these are just on a list
11 in 1441, just to be clear. I'm not
12 making these up, I'm just reading off a
13 list.

14 Q. So things that you need to
15 look at under 1441 would include looking
16 at the mesh, looking at the needle,
17 looking at the packaging, looking at the
18 accessories.

19 A. Looking at -- yeah.

20 Q. Cytotoxicity?

21 A. Looking at the
22 biocompatibility. It even says right
23 here, we're looking at the degradation of
24 the material. I didn't make that up.

1 That's right in the standard.

2 Biological safety test data.
3 Prior use. And right here it says, you
4 can use -- it says, Available information
5 on previous use. This is what I was
6 trying to be clear on.

7 It should be reviewed.

8 However, previous use of an ingredient or
9 material does not necessarily assure its
10 suitability in similar applications.

11 So that's really what I was
12 trying to state ahead of time,
13 beforehand.

14 MR. WALLACE: Before you ask
15 another question, let's take a
16 break.

17 - - -

18 (Whereupon, a brief recess
19 was taken from 2:06 p.m. to 2:17
20 p.m.)

21 - - -

22 (Whereupon, Exhibit Wilson 9
23 was marked for identification.)

24 - - -

1 BY MR. COMBS:

2 Q. Ms. Wilson, right before the
3 break we were talking about the risk
4 analysis.

5 And is the primary purpose
6 of risk analysis to identify potential
7 hazards?

8 I mean, is that why we're
9 doing it?

10 A. The primary reason for these
11 risk analysis is to produce a safe
12 product for people and eliminate sources
13 of harm.

14 Q. And so the goal of the risk
15 analysis is to produce the safest
16 product.

17 A. Yes.

18 Q. The risk analysis, that's an
19 engineering tool; correct?

20 A. It's a team tool. You need
21 a team to do a real -- a good job at
22 engineering analysis. It's not something
23 you can do in vacuum.

24 Q. And, earlier, you told us

1 about the use of the team. You have
2 members of the team that would bring
3 different specializations to the process.

4 A. Generally, they have a
5 leader. I have led quite a few teams of
6 different types of devices, and they do
7 have specialists in specific areas, like
8 design and clinical, for example.

9 Q. And the medical
10 representative on the team would be the
11 person that would give the primary input
12 regarding the medical risk; correct?

13 A. It depends. It depends on
14 the company and how they're structured.

15 Q. On the teams that -- strike
16 that.

17 Have you been involved in
18 risk assessments that have included
19 physicians?

20 A. We've had physician inputs,
21 and we have gone out. But often
22 marketing and clinical will bring that
23 medical input in.

24 Q. And why is it that you want

1 the medical input?

2 A. We generally get the
3 clinical input.

4 I say clinical, because it
5 may be a nurse, someone that goes out and
6 trains the physicians. So it's not
7 necessarily a physician.

8 To understand how it's used.

9 Q. And if a physician is part
10 of that team, that physician is giving
11 you expert input regarding their
12 knowledge of the medical or clinical
13 risk.

14 A. That's why often -- could
15 you restate that. I'm not sure I caught
16 it all. I'm sorry.

17 Q. If a physician is on the
18 team, that person is providing expert
19 input from their perspective regarding
20 the medical and clinical risk.

21 A. Right. If there is one.

22 Generally, like I just said,
23 you have a clinical person that works for
24 the company, and you have a marketing

1 person. You have the design person. And
2 you may have a, you know, medical adviser
3 that comes in just for a bit or reviews
4 it at the end.

5 Q. And the goal of the process
6 is to produce a safe product.

7 A. Right.

8 Q. On your reliance list, I did
9 not see any reference to any position
10 statements by physicians.

11 Is that correct?

12 A. Was this on my reliance
13 list?

14 Q. No, ma'am.

15 A. Because it doesn't look
16 familiar.

17 (Witness reviewing
18 document.)

19 MR. WALLACE: Can you repeat
20 the pending question, please.

21 MR. COMBS: I think the --
22 well, let's read it back.

23 - - -

24 (Whereupon, the requested

1 portion was read.)

2 - - -

3 BY MR. COMBS:

4 Q. So, Ms. Wilson, have you
5 ever reviewed the AUGS position
6 statement?

7 A. I'm just reviewing it right
8 now.

9 Q. Do you know what AUGS is?

10 A. I do not.

11 Q. AUGS is the American
12 Urogynecological Society. It's surgeons
13 that treat female pelvic floor disorders.

14 Do you know that?

15 A. No.

16 Q. Do you know what SUFU is?

17 A. Where is that? It's right
18 after AUGS.

19 Q. On the front page, the
20 right-hand column.

21 A. Society -- no. I don't know
22 of Urodynamics Female Pelvic Medicine.

23 This would be something I
24 didn't look at.

1 Q. And in determining whether a
2 product is safe, is one of the things
3 you'd want to know is what the surgeons
4 who use it believe about the product?

5 A. This could be another input
6 to that whole process and the team. But
7 I haven't read it all the way through,
8 but I certainly think it could be one of
9 the inputs.

10 Q. And TVT, its a midurethral
11 sling, isn't it?

12 A. (Gesturing.)
13 (Witness reviewing
14 document.)

15 Q. And the question was: Is a
16 TVT a midurethral sling?

17 A. I know it supports your
18 urethra. I don't know -- I believe I
19 said this before, I don't know exactly
20 where along the urethra, but --

21 Q. All right. I'll represent
22 to you the TVT is a midurethral sling.

23 A. Okay.

24 Q. The AUGS position paper at

1 the very top says, The procedure is safe
2 and effective and has improved the
3 quality of life for millions of women.

4 Do you agree or disagree
5 with that statement?

6 MR. WALLACE: Objection to
7 form. This hasn't been
8 authenticated.

9 THE WITNESS: And a white
10 paper, basically, anyone can write
11 a position paper.

12 As far as risk goes, you
13 have to evaluate all sources.

14 So you would have to make
15 sure that -- you know, this could
16 be one input. You would get
17 positions papers from around the
18 globe.

19 BY MR. COMBS:

20 Q. Here's --

21 A. That's all.

22 Q. Here's my question. Do you
23 disagree with AUGS that the procedure is
24 safe, effective, and has improved the

1 quality of life for millions of women?

2 Do you agree or disagree?

3 A. I have no way of answering
4 that question.

5 Q. At the bottom of the first
6 page, it says, The FDA website states
7 that the safety and effectiveness of
8 multi-incision slings is well established
9 in clinical trials that followed patients
10 for up to one year.

11 Do you agree or disagree
12 with that statement?

13 MR. WALLACE: Same
14 objection.

15 THE WITNESS: I have no way
16 of knowing this. I haven't
17 researched it. I have not done
18 anything to have any way of
19 knowing whether this is true or
20 not true.

21 BY MR. COMBS:

22 Q. On page 2, at the top, AUGS
23 says, Polypropylene material is safe and
24 effective as a surgical implant.

1 Do you agree or disagree
2 with that statement?

3 MR. WALLACE: Same
4 objection.

5 THE WITNESS: I have to give
6 you the same answer. I don't know
7 personally.

8 BY MR. COMBS:

9 Q. At the bottom of
10 paragraph 1, it says, As a knitted
11 implant for the surgical treatment of
12 SUI, macroporous, monofilament,
13 lightweight polypropylene has
14 demonstrated long-term durability, safety
15 and efficacy up to 17 years.

16 Do you agree or disagree
17 with that statement?

18 MR. WALLACE: Objection to
19 form. Same objection.

20 THE WITNESS: I can't agree
21 nor disagree.

22 BY MR. COMBS:

23 Q. You don't know.

24 A. I can't agree nor can I

1 disagree.

2 Q. Yeah. And that's because
3 you don't know whether that is a true or
4 an untrue statement.

5 A. I don't know if any of this
6 is true or not.

7 Q. Paragraph 2. The
8 monofilament polypropylene mesh
9 midurethral sling is the most extensively
10 studied anti-incontinence procedure in
11 history.

12 Do you agree or disagree
13 with that statement?

14 A. I don't have any way of
15 knowing.

16 Q. You don't know whether it's
17 the most extensively studied
18 anti-incontinence device in history, do
19 you?

20 A. No.

21 Q. At the bottom of paragraph
22 2, it says, Among historical SUI
23 procedures, the midurethral sling has
24 been studied as long in follow-up after

1 implantation as any other procedure and
2 has demonstrated superior safety and
3 efficacy. No other surgical treatment
4 for SUI before or since has been the
5 subject of such extensive investigation.

6 Do you agree or disagree
7 with that statement?

8 MR. WALLACE: Objection to
9 form. Same objection.

10 THE WITNESS: I believe I
11 stated several times that I'm not
12 a clinical expert and I'm not a
13 physician.

14 And my paper specifically
15 was to look at the risk process
16 and the design process.

17 This really, absolutely has
18 nothing to do with my whole paper
19 or my -- what I was asked to do.
20 It's like -- it's irrelevant to my
21 opinion.

22 BY MR. COMBS:

23 Q. Well, I understand you
24 believe that. But you don't know whether

1 that statement is true or untrue, do you?

2 A. I said in my opinion, this
3 has nothing to do with what I was asked
4 to do.

5 Q. So please answer my
6 question.

7 A. Okay.

8 Q. Do you know whether that
9 statement that I just read -- I will read
10 it again if you want.

11 A. Okay. Please do.

12 Q. Do you know whether that
13 statement is true?

14 A. Could you re-read it.

15 Q. Yes. I'm at paragraph 2,
16 the last two sentences of that paragraph.
17 So the first one.

18 Among historical SUI
19 procedures, the MUS, midurethral sling,
20 has been studied as long in follow-up
21 after implantation as any other procedure
22 and has demonstrated superior safety and
23 efficacy.

24 Do you know whether that's

1 true?

2 A. No. I don't know if it's
3 true.

4 Q. The next sentence.

5 No other surgical treatment
6 for SUI before or since has been subject
7 to such -- strike that.

8 The next sentence says, No
9 other surgical treatment for SUI before
10 or since has been subject to such
11 extensive investigation.

12 MR. WALLACE: Same
13 objection.

14 BY MR. COMBS:

15 Q. Do you know whether that's
16 true?

17 MR. WALLACE: Same
18 objection.

19 THE WITNESS: I don't know
20 if that's true.

21 BY MR. COMBS:

22 Q. Paragraph 3 says,
23 Polypropylene mesh midurethral slings are
24 the standard of care for the surgical

1 treatment of SUI and represent a great
2 advance in the treatment of this
3 condition for our patients.

4 Do you know whether
5 polypropylene mesh midurethral slings are
6 the standard of care?

7 MR. WALLACE: Objection to
8 form.

9 THE WITNESS: When it comes
10 to clinical things, I cannot
11 answer these questions.

12 Again, that's not my area of
13 expertise as noted in my report.

14 BY MR. COMBS:

15 Q. Ms. Wilson, in paragraph 3,
16 kind of near the bottom, there is -- it's
17 the next-to-last sentence.

18 Full-length midurethral
19 slings, both retropubic and
20 transobturator, have been extensively
21 studied, are safe and effective relative
22 to other treatment options and remain the
23 leading treatment option and current gold
24 standard for stress urinary incontinence.

1 Do you know whether that
2 statement is true?

3 A. I don't know.

4 MR. WALLACE: Same
5 objection.

6 BY MR. COMBS:

7 Q. Ms. Wilson, on the next
8 page, in the conclusion section, the last
9 sentence in that section says, This
10 procedure is probably the most important
11 advancement in the treatment of stress
12 urinary incontinence in the last 50
13 years.

14 Do you know whether that
15 statement is or is not true?

16 MR. WALLACE: Same
17 objection.

18 THE WITNESS: Same answer.

19 BY MR. COMBS:

20 Q. And the answer is you don't
21 know?

22 A. I don't know.

23 Q. Are these statements in the
24 AUGS position statement that we've just

1 gone over, are they something that a
2 physician would have more expertise in
3 relation to than you?

4 MR. WALLACE: Objection to
5 form.

6 THE WITNESS: I don't
7 understand your question.

8 Would a physician be more
9 interested in this?

10 BY MR. COMBS:

11 Q. No. Would they have more
12 expertise than you on the medical --

13 A. A physician is obviously a
14 clinical person. And I have stated I'm
15 not.

16 And it has no bearing on my
17 expertise to do what I was asked to do.

18 - - -

19 (Whereupon, a discussion was
20 held off the record.)

21 - - -

22 (Whereupon, Exhibits Wilson
23 10 and 11 were marked for
24 identification.)

1

- - -

2

MR. COMBS: Ms. Wilson, I

3

just wanted to put in the record

4

that we have done a lot of

5

questioning regarding EN 1441 and

6

EN 46001:1997. I just thought

7

they out to be in the record.

8

THE WITNESS: That's fine.

9

I'm thinking that there was

10

an earlier one we were talking

11

about prior to '97.

12

If you look on the

13

certificate -- is that the right

14

one?

15

MR. DAVIS: Yes.

16

THE WITNESS: Okay. I just

17

wanted to make sure.

18

Oh, yeah, because these are

19

my copies. Aren't they?

20

They came from these

21

binders?

22

MR. COMBS: No.

23

BY MR. COMBS:

24

Q. Ms. Wilson, before the last

1 break, you were pointing out to us things
2 that EN 1441 required to be in risk
3 analysis.

4 Do you remember that?

5 A. I believe I said that those
6 were things to consider, not required.

7 Q. Okay. My mistake.

8 You were pointing out to us
9 things that 1441 said to consider in risk
10 analysis; is that correct?

11 A. Right. They're in the
12 standard.

13 Q. And you pointed us to, for
14 example, Annex C as examples of possible
15 hazards that could be considered in a
16 risk analysis; is that correct?

17 A. In the design. I was
18 focusing on the design portion of it.

19 Q. And so for the design
20 portion of the risk analysis, you pointed
21 us to Annex C, which had things such as
22 biological hazards, environmental
23 hazards, hazard related to the use of the
24 device, hazards arising from functional

1 failure, maintenance, aging, things of
2 that nature; is that correct?

3 A. And many more. I think I
4 said mechanical forces and a variety of
5 things in there.

6 Q. Has a risk -- strike that.
7 Was a risk analysis done of
8 TVT pursuant to EN 1441?

9 A. As far as I know, there was
10 an application one done.

11 And then in 2001, I believe,
12 after this product had been on the
13 market, I did see a risk analysis per
14 1441.

15 However, that wasn't done in
16 the design. And that's what my report
17 goes back to, is during the design of the
18 device is when this is critical to be
19 done, not some years after the fact.

20 Q. Now, what is the 2001 risk
21 analysis that you're discussing? Because
22 it's not on the reliance list. That's
23 why I'm asking.

24 A. It is in that 500 --

1 THE WITNESS: Can you
2 explain that? I don't know if we
3 can. It was in a different Bates
4 number.

5 MR. WALLACE: Ethicon has
6 marked some of the same documents
7 with different Bates numbers. And
8 I think that's where the confusion
9 might lie.

10 But bottom line is -- I can
11 talk to you about that offline, if
12 you want, but I'm not going to sit
13 here and try to ferret through it
14 during this deposition.

15 MR. COMBS: Okay.

16 MR. WALLACE: She has
17 seen -- go ahead. She has seen --
18 go ahead.

19 THE WITNESS: I'm not sure
20 how to explain it. What I looked
21 at -- what's her name -- Ms. --
22 oh, my goodness, I'm drawing a
23 blank.

24 MR. WALLACE: Duncan.

1 THE WITNESS: -- Duncan's
2 report there was a reference to
3 the technical file, the numbers
4 didn't match up to my numbers.

5 So I took a double-check of
6 that. And when I did look at that
7 technical file, I'm like, oh,
8 yeah, but this was done in 2001.

9 I remember looking at these
10 things and it did have the same
11 Preventia documents in there. It
12 did have a 1441 in there. It said
13 to 1441.

14 However, in my opinion, it
15 was done after the device was --
16 you know, it was in 2001.

17 So if this was on sale in
18 '97, '98, 2000, maybe it was 2002,
19 even, that's not when the device
20 was being -- the primary design.
21 And it was more like when they
22 were talking about the blue mesh
23 time frame.

24 BY MR. COMBS:

1 Q. Now, that document is not on
2 your reliance list, is it?

3 A. Yes. I believe it's under a
4 different Bates number. That's what I'm
5 trying to say.

6 Q. Well, how do I find that? I
7 mean, I looked at the reliance list, and
8 it's not on there. But if you say it is,
9 I'd like to look.

10 A. Well, I'm sorry. I'm not an
11 expert on Bates numbers. We would have
12 to go to the Duncan report and
13 cross-reference it and bring that stack
14 of papers.

15 MR. WALLACE: Is your
16 question whether or not she has
17 previously seen the technical
18 file?

19 MR. COMBS: The first
20 question is: Is it on the
21 reliance list?

22 THE WITNESS: As we -- we
23 have a copy of her report?

24 BY MR. COMBS:

1 Q. Yes.

2 A. Let me see if I can go
3 backwards, because the numbers didn't
4 match up.

5 MR. DAVIS: Are you going to
6 make her reliance list an exhibit?

7 MR. COMBS: Isn't that in --

8 MR. DAVIS: It's not
9 attached to her report. Ask her,
10 I don't think it was.

11 MR. COMBS: This is 12.

12 - - -

13 (Whereupon, Exhibit Wilson
14 12 was marked for identification.)

15 - - -

16 THE WITNESS: (Witness
17 reviewing document.)

18 I'm not sure I can go
19 backwards. I'm not sure I'm smart
20 enough on Bates numbers to go
21 backwards.

22 But I looked at the
23 technical file. It was about
24 1,000 pages. So it was about 500

1 pages double-sided.

2 BY MR. COMBS:

3 Q. Which technical file?

4 A. For the TVT. It was labeled
5 as TVT-L, even though it says it was
6 TVT -- I don't know if they used standard
7 or which code word they used, but it was
8 the TVT base, maybe they said, and blue.
9 But it was about 1,000 pages.

10 And I know, you know, but I
11 might have to refer to our attorneys to
12 explain the Bates numbers.

13 Q. Okay. Would you agree with
14 me that nowhere in your report is there
15 any reference to a risk analysis from
16 2001 regarding TVT?

17 A. Right. I was talking about
18 my report talked about, like from the
19 very beginning, it talked about right
20 here, the design phase October '98, '93,
21 those kinds of time frames, because
22 that's when the device was being
23 designed.

24 And so I wasn't looking at

1 things that happened four years later as
2 part of the design.

3 Yeah, it's not in my report,
4 that counted.

5 Q. There's no mention in your
6 report of that, is there?

7 A. Right. The application
8 FMEA, which was done earlier in time, is
9 the one that I mentioned, because that
10 was during the design time frame.

11 Q. Did you purposely leave that
12 out of your report?

13 MR. WALLACE: Objection to
14 form. Assumes facts not in
15 evidence.

16 THE WITNESS: I didn't find
17 that to be of importance, because
18 it wasn't part of the design. I
19 was focusing, again, on the design
20 portion.

21 BY MR. COMBS:

22 Q. And in your report, are
23 there places in which you say -- okay.
24 Strike that.

1 That FMEA is not mentioned
2 anywhere in the report, is it?

3 A. No.

4 Q. And is that something that
5 you considered in forming your opinions
6 in this case?

7 A. It is. I mean, I looked at
8 it and I said in the very background
9 that, you know, in the summary, that they
10 were either not conducted or were not
11 able to demonstrate that they were --
12 wait. Let me find this.

13 So they either weren't there
14 or they weren't able to demonstrate they
15 were done in a manner that was good, in
16 my opinion.

17 So you don't come back --
18 and I have been asked to do this as a
19 consultant -- to come back later after
20 the product is on the market and say, oh,
21 by the way, can you make me a design
22 history file.

23 I have been asked to do
24 that. And, to me, that's just not good

1 practice. So I did not include that.

2 I considered it, and I
3 decided that that wasn't what's intended
4 to be done by these standards. And so
5 that's why it wasn't specifically called
6 out.

7 Q. So you made a decision to
8 exclude that risk analysis, because it
9 was done after the product had been
10 marketed.

11 A. I didn't exclude it. I
12 considered it. And right in here, I
13 said, you know, either it -- either it
14 wasn't conducted or it doesn't say that
15 it was -- the system functioned in a good
16 manner.

17 So I didn't think it was in
18 a good manner. So I didn't exclude it.

19 Q. Where in your report does it
20 say that the system didn't function in a
21 good manner?

22 A. It wasn't able to
23 demonstrate that the acquired system,
24 because it wasn't in the --

1 Q. And I apologize, ma'am.
2 Where are you reading?

3 A. I'm in the summary of
4 opinions, number 1, on page 3. I'm sorry
5 about that.

6 Q. So is it your basic position
7 that because that risk analysis is done
8 after the product was marketed, it
9 doesn't count?

10 A. No. What I'm trying to say
11 is, if it's not done during the design
12 phase, then you're not able to mitigate
13 risk and you're not able to make measures
14 to make it safer.

15 And so what you document
16 after the fact may not be adequate.

17 And so that is -- and, in
18 fact, I didn't feel it was adequate, so
19 that's why I made that statement.

20 MR. COMBS: All right. Mark
21 this as 13.

22 - - -

23 (Whereupon, Exhibit Wilson
24 13 was marked for identification.)

1

- - -

2 BY MR. COMBS:

3 Q. And is that the risk
4 analysis that you're referring to?

5 A. Let me take a look here.

6 MR. WALLACE: Phil, is this
7 from this 1,000-page document that
8 Ms. Duncan cites?

9 MR. DAVIS: Yes.

10 THE WITNESS: Yes, it is.

11 MR. COMBS: I don't know
12 what document she's citing. This
13 is from the technical file.

14 MR. WALLACE: So in other
15 words, Anne knows better than both
16 of us.

17 You're saying this is what
18 you saw yesterday.

19 THE WITNESS: Yes, because
20 the numbers didn't jive. And I
21 wanted to make sure it was the
22 same thing. And I didn't bring
23 all these boxes with me, so I did
24 specifically relook at this.

1 And, yeah, I remembered
2 seeing it, because I've never seen
3 anyone put "not imaginable."

4 BY MR. COMBS:

5 Q. And so did you get a hard
6 copy of this from counsel?

7 A. I asked for this to be
8 printed out yesterday, yes. And I had
9 seen it before.

10 Q. Did you have a hard --

11 MR. WALLACE: Let me be very
12 clear. When you say "before,"
13 before yesterday?

14 THE WITNESS: Correct.
15 Before yesterday.

16 BY MR. COMBS:

17 Q. You had a hard copy of it
18 before yesterday?

19 A. Let me try to be clear.

20 All documents were provided
21 to me electronically. I could choose
22 which ones to print out. And so as part
23 of my decision-making process, I scanned
24 things and then some I chose to print

1 out. Some I didn't.

2 I can't recall if I printed
3 this or I looked at it electronically.

4 Q. Will you provide Mr. Wallace
5 with a copy of the Bates stamp of the
6 document that you say this was within?

7 A. I'm sorry. I don't
8 understand the question.

9 Q. I have asked you today to
10 show me where it is on the reliance list.
11 And you say you can't. And so I'm
12 asking: Will you provide that
13 information to Mr. Wallace?

14 A. Of course. I'm sure it's
15 tracked down somewhere in one of the
16 computers.

17 Q. All right. So we marked a
18 copy of your reliance list as Exhibit 12.

19 A. Okay.

20 Q. And so you'll tell
21 Mr. Wallace where on this reliance list
22 this document is.

23 A. We'll figure that out. I
24 just don't know right off the top of my

1 head.

2 Q. Okay.

3 A. Because the numbers didn't
4 match up.

5 Q. And so you agree this is
6 risk analysis done pursuant to 1441?

7 A. Well, that's --

8 MR. COMBS: It's 13, Ed.

9 THE WITNESS: That's what
10 this says. I would not say that
11 it's -- you know, I would not
12 personally say.

13 In my opinion, it doesn't
14 meet what 1441 says to do. But it
15 says it's per 1441 there.

16 BY MR. COMBS:

17 Q. And would you agree with me
18 that nothing related to that is set forth
19 in your report?

20 Is there anywhere in your
21 report that you say this risk analysis
22 doesn't comply with 1441?

23 MR. WALLACE: Objection to
24 form.

1 THE WITNESS: No. It's not
2 going to say that in my report.

3 BY MR. COMBS:

4 Q. I mean, that's not contained
5 within the Rule 26 expert report of Anne
6 Wilson, is it?

7 MR. WALLACE: Objection to
8 form.

9 THE WITNESS: It says that I
10 looked at this big, giant
11 document, and in my opinion, that
12 it wasn't a design risk analysis
13 that was either present or
14 adequate. And that was my
15 opinion.

16 BY MR. COMBS:

17 Q. What does it say?

18 MR. WALLACE: Can I cut
19 through the chase?

20 MR. COMBS: Sure.

21 MR. WALLACE: Go back to
22 Summary of Opinion 1. Her entire
23 report references these issues.

24 I think what's happening is

1 you guys are like two ships
2 passing in the night right now.
3 Okay.

4 MR. COMBS: We're not two
5 ships passing in the night at all.
6 This document isn't on the
7 reliance list, and there is
8 nothing in the expert report --

9 MR. WALLACE: Well, first of
10 all, she said she's looked at it,
11 she's analyzed it.

12 She pointed to you ten
13 minutes ago, which you were not
14 on, how she says it either was not
15 there or it was inadequate, and
16 she told you that it was
17 inadequate. She even talked about
18 the unimaginable.

19 I am at a loss to understand
20 what you are insinuating here, but
21 I'm happy to work with you to
22 straighten it out.

23 But to sit here and ask the
24 same questions six times about

1 something not being here when she
2 told you 15 minutes ago before you
3 ever whipped out this Exhibit 13
4 that it was there and she talks
5 about 1,000-page document, and the
6 fact that she's seen this before
7 makes -- we're just not going to
8 allow the record to be this
9 muddled at this point.

10 BY MR. COMBS:

11 Q. Okay. Show me the sentence
12 that encompasses your opinion that this
13 does not comply with 1441.

14 Just show it to me so we can
15 read it into the record.

16 MR. WALLACE: You're asking
17 her to recite her entire report to
18 you.

19 She's talking about a risk
20 management process. She said she
21 reviewed the technical file. I
22 mean --

23 MR. COMBS: Ed, if we're
24 going to keep on with the speaking

1 objection like this, let the
2 witness step out of the room.

3 MR. WALLACE: Fair enough.

4 THE WITNESS: I need to use
5 the restroom.

6 MR. WALLACE: Let me finish.
7 I'm happy to step out of the room
8 with you. I agree with you. I
9 don't want to do a speaking
10 objection.

11 I'm just trying to cut to
12 the chase here, because I felt
13 like you guys are two ships
14 passing in the night, because
15 you're asking her to recite Bates
16 numbers, and she's already told
17 you she's not a lawyer.

18 MR. COMBS: Okay. Before we
19 break --

20 MR. WALLACE: Why don't you
21 take a break --

22 MR. COMBS: No.

23 BY MR. COMBS:

24 Q. Before we break --

1 MR. WALLACE: Oh, go ahead.

2 BY MR. COMBS:

3 Q. Before you break, I want you
4 to show me the portion of your report
5 that says, this risk analysis does not
6 comply with 1441. And the risk analysis
7 is Exhibit 13.

8 A. What I said here in Summary
9 of Opinion 1, which includes the summary
10 of the totality of my review of all the
11 documents, so whether it's got --
12 sometimes there's different numbers on
13 the documents, whether it was printed or
14 electronic, I looked at the document and
15 I very distinctly remember that, I said
16 I'm looking at the design, it was called
17 design -- I called it design history file
18 because that's the terminology used both
19 by Ethicon and also by the fact book.
20 And that was the time frame.

21 So I was looking for the
22 risk documents for the design in that
23 time frame.

24 And I said, look, in

1 October '98 through '99, until the
2 purchase in 2000, that was the time frame
3 I looked at, that the design
4 documentation, as outlined in the DHF, it
5 does not evidence the stuff that was
6 acquired.

7 So I'm saying, is there
8 evidence that the design documentation
9 including the risk complied? Right?

10 Q. What sentence are you
11 talking about?

12 A. I'm in the summary. I'm
13 paraphrasing paragraph 1.

14 Q. But I'm asking you not to
15 paraphrase. I want you to show me the
16 sentence that says, this risk assessment
17 doesn't comply with 1441.

18 A. That's not going to be
19 found.

20 Q. Okay. That's not in the
21 report.

22 A. That sentence that you're
23 trying to put into my mouth, I did not
24 write, because that was not my opinion.

1 It's part of the design --
2 was not conducted as part of the design
3 time frame.

4 Q. Okay.

5 A. So I will not write that
6 sentence. It's not going to come out --
7 I mean, you're trying to put words into
8 my mouth. That sentence is not in my
9 report.

10 Q. And so the failing of this
11 risk analysis is that -- the fact that it
12 was done after the product was brought to
13 market.

14 A. There were many failures.
15 If you would like me to go through those
16 after I use the restroom, I would be glad
17 to go through those.

18 MR. COMBS: Okay. We'll
19 take a break.

20 - - -

21 (Whereupon, a brief recess
22 was taken from 2:59 p.m. to 3:09
23 p.m.)

24 - - -

1 BY MR. COMBS:

2 Q. Ms. Wilson, you told us
3 earlier that you got documents from
4 counsel regarding this case.

5 You received them all
6 electronically?

7 A. Right.

8 Q. Were those on CD ROMs or
9 were they on share files?

10 A. I think they used Box, one
11 of those.

12 Q. A drop box?

13 A. Yeah. It wasn't Dropbox,
14 but one like that.

15 Q. All right. Did you get all
16 these at one time, or did you get them
17 over time?

18 A. There were several time
19 points. Large quantities at several time
20 points.

21 Q. Do you still have the share
22 files that you got?

23 MR. WALLACE: Any
24 communications between us are

1 protected. We filed some
2 objections. We can talk about how
3 to work that out, if you want
4 after the deposition.

5 MR. COMBS: I'm not asking
6 about communications, just asking
7 about whether the documents still
8 exist that were provided to
9 Ms. Wilson.

10 THE WITNESS: I generally
11 just delete them. I mean, I might
12 have some hard copies that printed
13 out. So back in my office I kept
14 hard copies of those that I chose
15 to print out.

16 I can't tell you which ones
17 I did and didn't right off the top
18 of my head.

19 BY MR. COMBS:

20 Q. So as we sit here today,
21 it's possible that you deleted them?

22 A. It's possible.

23 Q. And you don't know?

24 A. I don't know. I just don't

1 know.

2 MR. COMBS: Ed, I don't know
3 what to do about this risk
4 assessment, because, you know,
5 it's my position that it's not in
6 the report.

7 MR. WALLACE: Well, it's in
8 her entire report.

9 I mean, ask her whatever you
10 want. I mean, we can either
11 discuss this off the record in
12 front of her, out of her
13 appearance, or whatever.

14 But the bottom line is, it's
15 a very large part of her report.

16 So you want to talk about
17 it, you can talk about it all day
18 long, whatever time you have left.
19 It's up to you.

20 MR. COMBS: Well, no. The
21 bigger problem about it is, I
22 don't want you to take a position
23 that I have waived anything by
24 questioning her about it.

1 If I question her about it,
2 will you not take the position
3 that I waived anything?

4 MR. WALLACE: I'm sorry. I
5 don't even understand what you're
6 asking me. And I mean that.

7 MR. COMBS: My position is,
8 this risk analysis is not
9 discussed in this report.

10 If I question her about it,
11 are you going to take the position
12 that I have waived that?

13 MR. WALLACE: Well, you're
14 taking an absurd position, in my
15 opinion, but that's fine. We can
16 agree to disagree on that. Right?

17 MR. COMBS: So there won't
18 be any allegation I've waived
19 anything by questioning her on it?

20 MR. WALLACE: I have no idea
21 what you're even talking about
22 when you talk about waivers.

23 So I mean, if you're talking
24 about a second bite at the apple

1 in terms of another deposition or
2 all these other sorts of things,
3 those are things that we can
4 discuss outside the deposition.

5 MR. COMBS: That's fine.
6 Just as long as I am not waiving
7 anything by questioning her about
8 this document. That's all I'm
9 asking.

10 MR. WALLACE: If I
11 understood waiver, I would be able
12 to speak to that. But I
13 think Judge Goodwin would agree
14 with this, we need to try to be
15 fair with each other, so --

16 MR. DAVIS: I think she said
17 she has opinions. If she has
18 opinions, is that a waiver?

19 MR. COMBS: Ms. Wilson says
20 she has opinions about this
21 document.

22 MR. WALLACE: Well, of
23 course, because she authored a
24 Rule 26 report.

1 MR. COMBS: Okay. And I
2 want to ask her about those
3 opinions. It's my position that
4 they're not contained in this
5 report.

6 MR. WALLACE: Well, you're
7 making a mistake. So you'd better
8 ask questions about that document.

9 MR. COMBS: And there is
10 not -- because I'm fine with just
11 stopping the deposition at this
12 point and we can get the judge.

13 MR. WALLACE: I don't
14 understand why you would stop a
15 deposition when the witness has
16 said she reviewed the report and
17 considered the report in forming
18 her opinions.

19 MR. COMBS: That's the only
20 thing I'm -- that my
21 questioning --

22 MR. WALLACE: You don't
23 dispute that; right?

24 MR. COMBS: If I'm

1 questioning her on this document,
2 that you're not saying that I've
3 waived any right to object --

4 MR. WALLACE: You can argue
5 whatever you want to argue. You
6 and I can agree to disagree,
7 though, that this is a part of her
8 report.

9 She has said to you, I
10 looked at this and I looked at
11 this previously.

12 And she pointed to you
13 before you ever whipped that
14 document out, by the way, she
15 pointed at Summary of Opinions 1,
16 and was talking about it. Okay.

17 And then you brought this
18 out, which she said, absolutely,
19 she cited to you the whole not
20 imaginable thing or whatever the
21 heck she was talking about on
22 that.

23 So I tend to disagree with
24 your position. I think it's a

1 little bit far afield. Okay.

2 But you don't have to agree
3 with me on that.

4 But I suggest to you that
5 we're here for her deposition.
6 We're not going to come back. So
7 you'd better ask her whatever
8 you're going to ask her.

9 MR. DAVIS: We just agree.
10 If we think her opinion that she's
11 going to give us is not in the
12 report, and we disagree, we're not
13 waiving any right we might have.

14 MR. COMBS: That's all we're
15 asking.

16 MR. DAVIS: We're not asking
17 you to agree with us. We just
18 want you to agree that we're not
19 waiving our position.

20 MR. WALLACE: Why don't we
21 do this. Let's go off the record
22 for a second. If we need to go
23 back on, we'll go back on.

24 - - -

1 (Whereupon, a discussion
2 was held off the record.)

3 - - -

4 (Whereupon, a brief recess
5 was taken from 3:14 p.m. to 3:22
6 p.m.)

7 - - -

8 MR. WALLACE: Can we go back
9 on the record.

10 So, Phil, you and I talked
11 off the record. And what I
12 understand to be the case is your
13 position that the part of the
14 technical file is not included in
15 this report, and you understand
16 that we disagree with that as does
17 Ms. Wilson.

18 In fact, she just spent
19 several hours testifying about
20 technical files and design files,
21 and told you she reviewed and
22 considered this document.

23 And you want to ask
24 questions about it. And I'm

1 specifically referring to
2 Exhibit 13.

3 And I will agree with you
4 that you can and certainly should
5 ask questions about it, and that
6 by doing so, I'm not suggesting
7 that you can't maintain your
8 position that it's not included.

9 So is that satisfactory?

10 MR. COMBS: Absolutely.

11 Thank you.

12 BY MR. COMBS:

13 Q. Ms. Wilson, I have some
14 questions now for you about Exhibit 13.
15 It's right there at your left hand.

16 A. Okay.

17 Q. Now, it's my understanding
18 that you think that -- strike that.

19 What's your understanding of
20 what this document is.

21 A. What I understand it to be
22 is a risk assessment to 1441 that was
23 part of the design review, and that it
24 was signed off in 2001, which -- let me

1 check the exact date.

2 It says August 5th, 2001,
3 and it says, Is this product -- Is safety
4 product adequate?

5 So it was also nearby some
6 other DDSA and the Preventia documents
7 within that technical file.

8 So, basically, it's a
9 retrospective -- in my opinion, a
10 retrospective analysis of the design
11 risk.

12 Q. And when was this analysis
13 performed?

14 A. Well, the only date I see on
15 it was in 2001.

16 And then there was a cover
17 memo attached to it about the blue that
18 says it's still adequate for the blue
19 mesh. And that was -- oh, gosh, it's
20 hard to read, but it looks -- I don't
21 know if you can read any better, maybe
22 December of 2002. It's like an extra
23 digit, but it looks like August 5th of
24 2001 maybe.

1 Q. So approximately August of
2 2001.

3 A. Right.

4 Q. And it's your understanding
5 the purpose of this, that it was to
6 assess the risk of TVT clear?

7 A. Right.

8 Q. And then was used
9 subsequently as part of the risk
10 assessment for TVT blue?

11 A. Well, there was just a memo
12 that said this also counts as blue.

13 Q. Because of a conclusion had
14 been reached that there were no new risks
15 presented by TVT blue.

16 A. Yes. That's what it says.

17 Q. Now, it's your position that
18 this -- I'm paraphrasing, but it's your
19 position this doesn't count because it's
20 done after Ethicon assumed the
21 manufacture of the product?

22 A. No. That's not my position.

23 Q. Okay. So what is your
24 position?

1 A. I was waiting for your
2 question.

3 So what my position is, is
4 that, ideally, you would look at the
5 design of the product in the design
6 phase.

7 You can go -- with this, so
8 I think it's a remediation effort,
9 because it was found delinquent. There
10 was a later remediation effort when they
11 did the legacy products.

12 You know, I don't know what
13 their intent was, but it looks to me,
14 like in 2001, they went back and said,
15 we'd better look at this -- to our DDSA
16 procedure.

17 It's not exactly to that,
18 but to the best of my ability, to look at
19 it, because it doesn't exactly meet it.

20 They do have this risk class
21 on a 1 through 6, and the risk class is a
22 1 through 6 in the DDSA procedure.

23 So the adequacy of it, I
24 haven't talked about yet. But that's

1 what I think it is. It's a couple of
2 years after the design was out, they came
3 back and back-documented.

4 Q. And Ethicon assumed the
5 manufacture of the product in third
6 quarter of 2000?

7 A. I have to go back and check.

8 Q. Can we agree it was in 2000?

9 A. It says, April 1999, Ethicon
10 purchases Medscand.

11 Q. When did Ethicon begin the
12 manufacture of the product?

13 A. I'm not sure, but they were
14 responsible as soon as they purchased it.
15 So...

16 Q. Do you know who manufactured
17 the product between 1999 and the third
18 quarter of 2000?

19 A. I know they moved it to
20 their facility somewhere in -- it says,
21 And moved production to Ethicon SARL.
22 Actually, I have it September of 2000.

23 So I'm not a hundred percent
24 sure what happened between April 1999 and

1 September 2000, where that was made.

2 Q. You made a statement
3 regarding the procedures, and you made a
4 reference to the DDSA.

5 Do you know what procedure
6 governed this risk analysis?

7 A. You know, it appears to me
8 that because of the form that was after
9 it in the technical file -- you know,
10 there was another form after it, that was
11 DDSA, it looked like, and so that -- the
12 DDSA was called out in my report as OP --
13 sorry. Sometimes I get 10 and 11 mixed
14 up. OP650-10 is the DDSA.

15 Q. And is it your understanding
16 that this assessment was done pursuant to
17 that procedure?

18 A. That's my assumption, yeah,
19 because they used a form next to it.

20 And because the other thing
21 that made me assume that, is because
22 right at the back it said, Is the safety
23 adequate?

24 Q. Would you agree with me that

1 this analysis states that it was done
2 pursuant to 1441?

3 A. It does state that, yes.

4 Q. And would that have been the
5 proper standard to have done the Risk
6 Analysis 2 in August of 2001?

7 A. Let me check.

8 Well, at that point in time,
9 EN ISO 14971 had been issued. Now, I am
10 not sure if it had already been enforced.
11 So I would have to go back and
12 double-check, because there's transition
13 dates.

14 MR. WALLACE: Can you read
15 back the question, please.

16 - - -

17 (Whereupon, the requested
18 portion was read.)

19 - - -

20 THE WITNESS: Yes. EN 1441
21 was appropriate. Yes, because in
22 June the date of publication --
23 it's really close there.

24 It supercedes 1441:1997.

1 The date of publication was
2 June 30, 2001.

3 And we're talking now what
4 date again? I'm sorry.

5 We're right in the
6 transition. I think we're
7 right -- and the standards are so
8 similar, it's not really not worth
9 a minute to talk about, so...

10 BY MR. COMBS:

11 Q. All right. So you don't
12 have issue with the procedure, with the
13 ISO standard that is used for the basis
14 of this?

15 A. No, I don't.

16 Q. Now, would you agree that in
17 this risk analysis, that hazards were
18 identified?

19 A. We did look at some hazards.
20 Some hazards were defined.

21 Q. And, in fact, seven pages of
22 hazards.

23 A. You say that with a laugh,
24 but many of these are 20 to 50 pages.

1 So seven pages is really not
2 much at all.

3 Q. And would you agree that it
4 looked at hazards regarding the device
5 itself?

6 A. When you say "device," are
7 you talking mesh or the system? I'm just
8 not clear.

9 Q. Okay. Were hazards reviewed
10 regarding the mesh?

11 A. For example, 13(c) says,
12 Mesh will be fixated. So yes.

13 Q. And were hazards reviewed
14 regarding the tools?

15 A. I'm trying to find one. It
16 doesn't appear systematic to me. So it's
17 challenging to find it exactly where.

18 Q. So, for example, at
19 number 19, were the quantitative
20 properties for the device looked at?

21 A. It is a hazard, but there's
22 nothing written in. There's no failure
23 rate. There's -- it's very incomplete is
24 what I would say. There is a hazard with

1 nothing else in there.

2 Q. And below that, at AAA, for
3 example, needle strength was reviewed.

4 A. Again, there's a hazard, but
5 there's no mitigation.

6 So what you're saying is
7 partially true, in my opinion. It is
8 not -- tell the complete story.

9 Q. And were hazards reviewed
10 regarding the surgical complications,
11 could be related to the procedure?

12 A. I'd like to say that hazards
13 were listed. They weren't necessarily
14 reviewed, because there wasn't -- the
15 guidance says you don't just list a
16 hazard, you evaluate and you analyze
17 these hazards.

18 And in many of these cases,
19 they were listed, and that was it. There
20 was no failure rate, severities,
21 mitigations, risk priority numbers.

22 And that's the basis where I
23 think it's inadequate. And that's why I
24 put that -- why I went on in my report.

1 Q. Okay. And so for hazards,
2 they're in the analysis, they looked at
3 the failure mode, didn't they?

4 A. Where are you looking? I
5 just don't know what number. I'm trying
6 to --

7 Q. Failure mode, right at the
8 top.

9 A. Okay.

10 Q. They looked at probability
11 of occurrence?

12 A. On some of them, you're
13 right.

14 Q. Looked at risk class?

15 A. (Gesturing.)

16 Q. You have to say "yes" or
17 "no." You have to say something so she
18 can type it. You can't just nod.

19 A. Oh, I'm sorry. I was
20 shaking my head.

21 Right. On some of these,
22 they did say fill in the blanks, and
23 others, they did not.

24 Q. And they looked at

1 applicable safety measures?

2 A. That was a column, yes.

3 Q. They looked at other hazards
4 generated?

5 A. Yes.

6 Q. Looked at risk class?

7 A. They assigned a risk class
8 where they had some data. Other times,
9 they did not. They just left it blank.

10 Q. And they assessed the
11 remaining risk at the end of the
12 remediation?

13 A. Again, they did that in some
14 cases, but in others they didn't. That
15 column header was present.

16 Q. And do you know what the
17 frequencies were for the probabilities of
18 occurrence?

19 Like, for example, rare, do
20 you know what that means?

21 A. What you would have to do.
22 Generally, there's a risk plan.

23 No. Off the top of my head,
24 I don't. I would have to go track it all

1 down to the procedure in force at that
2 time of day.

3 Q. And for all of the rest of
4 the categories, you wouldn't know what
5 those were either.

6 For example, you wouldn't
7 know what the frequency was for
8 occasional, frequent, probable.

9 A. I know what often companies
10 used, but I can't tell you if frequent is
11 1 in 10,000 in this case or 1 in 1,000.

12 Q. Is part of your assessment
13 of this risk analysis, you didn't look at
14 that issue?

15 A. You know, I did look at
16 this -- that issue. And, generally, it's
17 a numerical. If you go look at the --
18 we'd have to go look at the procedure.

19 But the manufacturer is
20 supposed to come up with a risk plan, and
21 in that they're supposed to say, or you
22 go back to that procedure and it says,
23 you know, one -- this was not a dFMEA in
24 accordance with the dFMEA procedure.

1 But you're supposed to give
2 a number, so that it can be multiplied
3 and come up with a risk priority number.

4 So this isn't a dFMEA.

5 Q. Does this risk analysis
6 review risks related to the design of the
7 device?

8 A. It reviews some of them,
9 yes. And then others, it leaves entirely
10 blank.

11 Q. And does this risk analysis
12 look at ways in which to remediate the
13 risk?

14 A. In some cases it does, and
15 in others it doesn't.

16 MR. COMBS: We'll mark these
17 collectively as Exhibit 14.

18 - - -

19 (Whereupon, Exhibit Wilson
20 14 was marked for identification.)

21 - - -

22 BY MR. COMBS:

23 Q. Ms. Wilson, I have handed
24 you what we have marked as Exhibit 14.

1 And take a second to look at that.

2 MR. DAVIS: Do you mind if I
3 look through this.

4 THE WITNESS: No, go right
5 ahead. I think it's the same as
6 this morning.

7 MR. COMBS: Yeah, but we
8 didn't have time to look at it
9 this morning.

10 THE WITNESS: (Witness
11 reviewing documents.)

12 BY MR. COMBS:

13 Q. Ms. Wilson, have you had a
14 second to look at what is in the exhibit?

15 A. Briefly.

16 Q. Let's go through these. And
17 I want to find out if -- so the first one
18 we have is Preventia Revision 5.

19 Is that something that you
20 reviewed?

21 A. No. I don't recall anything
22 earlier than 7, like I said this morning.

23 MR. DAVIS: Can I just ask
24 one second, would you all mind,

1 while we're doing this, if I go
2 get these standards copied?

3 MR. WALLACE: Go ahead.

4 THE WITNESS: Some of those
5 are just a summary of notes I
6 made.

7 MR. DAVIS: I understand.

8 BY MR. COMBS:

9 Q. And next we got Preventia 7.
10 And is that something that
11 you reviewed?

12 A. Let me just check.

13 Q. That's the one you corrected
14 me earlier.

15 A. Yeah. Seven and 8 I do
16 believe I reviewed.

17 Q. The report says that the
18 only one that existed was 8, but you
19 had --

20 A. And then I said --

21 Q. -- in fact reviewed 7.

22 A. Yeah.

23 Q. Then the next one, the DDSA
24 pursuant to OP650-010 --

1 A. Let me look at that.

2 Q. -- had you reviewed that?

3 A. Let me take a look,
4 because -- I need to take a look at it.

5 This is a different device
6 than the TVT-R. This is the TVT-AA,
7 which utilizes a different -- as far as I
8 understand it, it uses a different
9 surgical technique, and it also uses some
10 different guides and couplers.

11 So this is outside the scope
12 of my analysis.

13 Q. So this is something you did
14 not consider?

15 A. I did see it, and I decided
16 that it wasn't relevant to my report. I
17 mean, I remember seeing this and saying,
18 oh, this is the AA, and it's not within
19 the scope of my report.

20 Q. Do you know whether the
21 TVT-AA uses the same mesh as TVT?

22 A. It's my understanding that
23 it uses the same -- I'd have to check
24 whether it was laser cut or not. That's

1 one thing I'm not fully clear on.

2 But as far as I understand
3 it, it's not the same accessories or the
4 same surgical technique.

5 Q. Do you know what the
6 difference is between surgical technique?

7 A. I'd have to put them side by
8 side. But I did review it at one point
9 in time.

10 Q. So this is the something
11 that you had, but something you excluded
12 as not relevant.

13 A. I said it didn't meet the
14 intent or the scope of my project, so I
15 didn't specifically call it out.

16 Anything that wasn't within
17 the mechanical cut TVT-R would be in that
18 same bucket.

19 Q. Okay. And so we have got
20 the risk management for TVT laser cut
21 mesh.

22 A. Mm-hmm.

23 Q. And that's

24 ETH.MESH.10618731.

1 Is that something that you
2 had?

3 A. I had the laser cut, I
4 believe. And it was a different
5 manufacturer process. And we talked
6 about that.

7 Q. And so that's something that
8 you excluded from your analysis.

9 A. And that's very -- if you
10 look at my report, on page 2, I'm very
11 specific that this is only Prolene
12 polypropylene mesh for the TVT-R
13 mechanical cut.

14 Q. And so you did not consider
15 that for any part of the bases of your
16 opinions for this report.

17 MR. WALLACE: Objection to
18 form. Asked and answered.

19 THE WITNESS: I was aware of
20 documents regarding laser cut.
21 And I said, jeez, that's not what
22 I'm asked to look at.

23 So if I'm asked to do laser
24 cut, I'll work on the laser cut.

1 BY MR. COMBS:

2 Q. Okay. But that did not form
3 the basis for any of the opinions that
4 are in your report.

5 A. Right.

6 Q. Now, the next document we
7 have is we have the design FMEA for TVT
8 laser cut mesh project.

9 A. It's the same answer.

10 Q. That did not form any basis
11 for any of the opinions in your report.

12 A. Right.

13 Q. And we have got the risk
14 management report for TVT laser cut mesh.
15 And that's Bates Number 00309260.

16 Same answer?

17 A. Well, let me -- I'm trying
18 to rethink what you might be asking.
19 Because I'm looking at things that
20 happened to the TVT-R.

21 I know I looked at things
22 laser cut. I also know that they weren't
23 necessarily implemented in TVT-R.

24 So I did consider them. But

1 you asked did they form the basis of --

2 Q. Did they form the basis of
3 any of the opinions in your report?

4 A. Can you -- I'm not sure I
5 understand that word choice.

6 I'm sorry. I'm not trying
7 to be difficult. They -- specifically,
8 in here, there were things that were
9 considered.

10 MR. WALLACE: When you say,
11 "in here," can you point to what
12 you're --

13 THE WITNESS: Sure.

14 For example -- it might be
15 easier that way.

16 When we're talking about
17 particle loss, there were some
18 documents that compared the
19 particle loss with, you know, blue
20 mesh versus not blue mesh, and
21 laser cut might have been stiffer
22 than non-laser cut.

23 So I was aware of them, but
24 I kept my focus on the TVT-R.

1 BY MR. COMBS:

2 Q. Was particle loss ever
3 studied in one of the risk analysis
4 documents that you reviewed?

5 A. Not that I used for this
6 report. I didn't study the risk analyses
7 for these.

8 MR. WALLACE: Just so we're
9 clear, you're pointing at
10 something?

11 THE WITNESS: I'm sorry.

12 MR. WALLACE: Just so we're
13 clear, can you tell the court
14 reporter what you're pointing at.

15 The laser cut Exhibit 14?

16 THE WITNESS: Right. So
17 Exhibit 14 has laser cut
18 documents.

19 BY MR. COMBS:

20 Q. Well, it has other documents
21 in it, too. I mean, we have been going
22 through and talking about them and
23 identifying them as we have been going
24 through.

1 A. Which -- the one that you
2 were just asking me about was about laser
3 cut.

4 Q. Okay.

5 A. And I do not have the title
6 of that right now.

7 Q. Ms. Wilson, that's RMR17.

8 A. I did not study the RMR17
9 document.

10 Q. And then the next document,
11 Risk Management Report Legacy for TVT and
12 TVT-O, ETH.MESH.10618757.

13 A. Can you just tell me the
14 Bates number? That would be easier for
15 me.

16 Q. ETH.MESH.10618757.

17 A. 1061873.

18 Q. 10618757.

19 A. Oh, I looked at this, and I
20 referred to it in my report. The 44,
21 yeah.

22 Q. The application FMEA for TVT
23 classic, ETH.MESH.10618418.

24 A. What was the date on that

1 one? 2010?

2 Q. Yes, ma'am.

3 A. Yes. I saw that.

4 Q. Is that one of the things
5 you considered in your report?

6 A. Well, you know, I did look
7 at that. But there was a new -- yes, I
8 did look at this.

9 Q. That's not set forth in your
10 report, is it?

11 A. I'm pretty sure that I had
12 it in my list of documents, that I looked
13 at all of the legacy things.

14 Q. But that's not listed in the
15 report. It's not listed in your
16 opinions.

17 A. My opinions don't call out
18 every single document, item by item, and
19 give an opinion based on every single
20 document I reviewed.

21 It's a summary of my overall
22 opinion, and it does bring up the things
23 that I believe were important and omitted
24 or not contained.

1 But it wasn't an
2 accountability of every document, good,
3 bad, yes, no.

4 You know, this is a 2010
5 version, but, you know, after they did
6 the legacy.

7 Q. All right. And then we have
8 got the risk management report for laser
9 cut mesh, and we have got Revision 3?

10 A. Again, that's laser cut, so
11 I didn't use that.

12 Q. Do you know whether you
13 looked at that?

14 A. I did not specifically look
15 at it.

16 Q. And then we have got the
17 risk management report for TVT and TVT-0
18 Revision 2.

19 A. That, let me check it out.
20 Let's see. I see Revision 3 here.

21 Yeah, any of these that are
22 44s, I did look at, whether it was 1, 2,
23 or 3.

24 Q. Now, on page 15 of your

1 report, you state, No dFMEA had been
2 performed on the TVT-R to date.

3 Now, would you agree with me
4 that the 2001 risk assessment -- risk
5 analysis had, in fact, evaluated risk
6 related to the design of TVT?

7 A. Let me just find where
8 you're talking about.

9 Q. In the middle paragraph on
10 page 15.

11 MR. WALLACE: Can you call
12 out the language again, Phil.

13 MR. COMBS: Yeah.

14 THE WITNESS: Oh, right
15 here. No dFMEA.

16 And that's true. No dFMEA
17 had been.

18 BY MR. COMBS:

19 Q. And would you agree with me
20 that the risk analysis that was performed
21 in 2001 had analyzed risks related to the
22 design of TVT?

23 A. I think it was wholly
24 inadequate, and it did not fully look at

1 the design, and it was not an FMEA.

2 Q. I understand that's what
3 you're saying, but that's not the
4 question I asked you.

5 The question I asked you
6 was: Would you agree with me that the
7 risk analysis reviewed risks related to
8 the design of TVT?

9 A. It looked at some. It was
10 not a dFMEA, which is what I wrote.

11 Q. Would you agree with me that
12 the risk analysis from 2001 reviewed some
13 of the risks of the design of TVT?

14 A. It's the same that I just
15 answered. I didn't change my mind.

16 Q. Okay. What's the answer
17 then?

18 A. That that was not a dFMEA
19 and it did not look at the risks
20 associated with the design.

21 Q. Okay. That analysis does
22 not look at risks associated with the
23 design --

24 A. It looked at some. It left

1 a lot of things blank and --

2 Q. That was my question. My
3 question was: Did it look at some of the
4 risks of the design of TVT?

5 A. It looked at some.

6 MR. WALLACE: Off the
7 record.

8 - - -

9 (Whereupon, a discussion was
10 held off the record.)

11 - - -

12 (Whereupon, a brief recess
13 was taken from 3:58 p.m. to 4:03
14 p.m.)

15 - - -

16 (Whereupon, Exhibits 15 and
17 16 were marked for
18 identification.)

19 - - -

20 BY MR. COMBS:

21 Q. Ms. Wilson, I hand you
22 what's been marked as Exhibits 15 and 16.

23 A. Okay.

24 Q. Those are audit reports from

1 TUV audits in 2003 and 2004.

2 A. Okay.

3 Q. Have you reviewed those
4 before today?

5 A. I don't recall seeing them.
6 They could have been in the stack of
7 papers, but I don't recall it.

8 Q. You don't recall seeing it.
9 And I have given you --
10 well, strike that.

11 Do you know how many times
12 Medscand was audited by a notified body?

13 A. I don't know that
14 specifically.

15 Q. Do you know how many times
16 Ethicon has been audited by a notified
17 body regarding TVT?

18 A. Worldwide. I don't --

19 Q. Regarding TVT.

20 A. I really don't know that.

21 Q. Do you know how many times
22 Ethicon has been audited by the FDA
23 regarding TVT?

24 A. I don't know that. Because

1 the FDA doesn't audit, and they don't
2 usually do -- I don't know.

3 Q. I have given you Medscand
4 audits from the late 1990s, Ethicon audit
5 from 2000, Ethicon audit for 2003,
6 Ethicon audit for 2004.

7 A. May I clarify?

8 Q. Yes, ma'am.

9 A. I think the early -- the
10 Medscand, you gave me the certificates.
11 I didn't see any --

12 Q. Okay. And have you gone
13 back to get the reports related to those
14 audits?

15 A. That wasn't the focus of my
16 report. So I did see those in the tech
17 file, and that was that.

18 Q. All right. You're not aware
19 of any audit ever coming to the
20 conclusion that degradation was a risk,
21 are you?

22 A. A notified body?

23 Q. Yes.

24 Internal audit, notified

1 body audit, regulatory body audit.

2 A. All right. That's why I
3 asked.

4 Let me look at my report.

5 Because "audit" is a very
6 broad term. Do you also include
7 inspections in that?

8 I mean --

9 Q. Okay.

10 A. An audit -- say it again.
11 Am I aware --

12 Q. Are you aware of any audit
13 of the auditor ever reaching the
14 conclusion that degradation presented a
15 clinical risk?

16 A. That is not what an auditor
17 would look for. Auditors don't look for
18 cause and effect of a clinical outcome.

19 Q. Are you aware --

20 A. So the question is not
21 making sense yet.

22 Q. Are you aware of any audit
23 in which an auditor concluded that the
24 risk analysis had failed to properly

1 consider the risk of degradation?

2 A. That question also doesn't
3 make sense to me.

4 I only saw -- let me try
5 this way.

6 I saw two internal audits
7 conducted by Ethicon of Medscand. So
8 those are the only two that I have seen.

9 And this morning I talked
10 about those. Otherwise, I haven't seen
11 other audits, per se.

12 Q. And those internal audits
13 did not come to the conclusion that
14 degradation presented any risk, did they?

15 A. They were not that specific.
16 They were much more vague.

17 Q. And they did not come to the
18 conclusion that roping, curling, or frame
19 presented any clinical risk that
20 outweighed the benefits of the product,
21 did they?

22 A. That is not how audits are
23 performed. That doesn't make sense for
24 an auditor to come to a conclusion such

1 as that.

2 Q. And there was no finding
3 that the risk of particle loss exceeded
4 the benefits of the product, was there?

5 A. Once again, that's not how
6 audits worked. We talked about how
7 audits work. They audit to standards.
8 They don't audit to clinical outcomes,
9 like you're trying to tell me.

10 So they audit and say, Do
11 you have a system in place? And do you
12 have evidence?

13 But they don't say what
14 we're trying to say that they would do.
15 That's just not how audits work.

16 Q. Exactly. They look at the
17 process, don't they?

18 A. Right.

19 Q. And so they look at whether
20 the process has been followed, don't
21 they?

22 MR. WALLACE: Objection to
23 form.

24 THE WITNESS: What auditors

1 do, I explained this morning, is
2 that they look at a standard or a
3 set of standards.

4 They go in. They look how
5 you established to those, and then
6 you look at how you deployed to
7 those.

8 So you may have established
9 well and deployed totally poorly.
10 But they don't do apples to
11 oranges, like you were trying to
12 ask me or like you asked me.

13 - - -

14 (Whereupon, Exhibit 17 was
15 marked for identification.)

16 - - -

17 BY MR. COMBS:

18 Q. Ms. Wilson, I hand you what
19 has been marked as Exhibit 17.

20 What is that?

21 A. It says it's a Device Design
22 Safety Assessment Re-Evaluation.

23 Q. And is this one of the
24 documents that you discuss in your

1 report?

2 A. I do. And I stated that
3 this was really a complaint analysis
4 rather than a DDSA.

5 Q. Now, had the risk that
6 Ms. Meltzer talked about in this, had
7 they been the subject of the risk
8 analysis done in 2001?

9 A. These risks she said are new
10 risks. And that's why I call them new
11 risks.

12 And if you look right here,
13 they said, Were they previously listed in
14 the DDSA, yes or no? And the answer for
15 many of them, the ones I cited in my
16 report, and this is key to why I wrote my
17 report like I did, is that they weren't.

18 So in the DDSA, it says
19 right here, No, they weren't in there.

20 Q. But that wasn't my question.
21 My question was --

22 A. I thought it was.

23 Q. It was not.

24 My question was: Are these

1 risks and risk analysis that was
2 performed in 2001?

3 A. Let's go double-check. I
4 don't believe so.

5 I'm thinking I this at one
6 time, but it's been a couple months and I
7 just can't remember everything.

8 Q. Let me start take a step
9 back for a second.

10 Is it your opinion that
11 these risks, the 11 risks that are set
12 forth in these memorandum, that these
13 were risks that Ethicon was not aware of?

14 A. Right. And that's what I
15 stated in my report, because it said
16 right here that they were new and they
17 were not in the DDSA.

18 So I took that as factual,
19 as written by their employees, yes.

20 Q. So it's your opinion that
21 Ethicon was unaware of these risks.

22 A. I just took what Ethicon
23 wrote and believed it to be true.

24 I also think I went back and

1 checked to this and the Medscand -- or
2 the Preventia. But I can't remember
3 every little cross-reference sheet.

4 MR. DAVIS: Let the record
5 reflect that this reference was to
6 Exhibit 13.

7 BY MR. COMBS:

8 Q. And so, for example, the
9 first one, Vaginal Extrusion.

10 Was postoperative erosion of
11 vagina one of the risks analyzed in the
12 2001 risk assessment?

13 A. I just answered this three
14 times. I'll have to go compare, so
15 please give me some time.

16 Q. That's fine.

17 MR. WALLACE: To speed this
18 along, do you mind if I help?

19 MR. COMBS: I don't mind at
20 all. It's 28N, it's the last
21 page.

22 THE WITNESS: That has no
23 risk. A rank of zero.

24 BY MR. COMBS:

1 Q. Was it --

2 A. It is listed here. Yes. I
3 see that now.

4 Q. And is the remediation for
5 that risk info in IFU in training?

6 A. That's what it says, yes.

7 Q. Now, was urethral erosion
8 analyzed in that risk analysis? 28L.

9 A. There was injury to the
10 urethra.

11 Q. On 28L, postoperative
12 erosion to the urethra.

13 A. I see that listed.

14 Q. And was remediation proposed
15 for that information in IFU in training?

16 A. That's what this says.

17 Q. And perforation by mesh on
18 the risk analysis has both postoperative
19 erosion of both the urethra and the
20 vagina?

21 A. So these two documents are
22 directly contradictory, and I looked at
23 this.

24 MR. WALLACE: Here.

1 What was your question?

2 BY MR. COMBS:

3 Q. My question is: The risk,
4 perforation by mesh, does the risk
5 analysis look at the risk of
6 postoperative erosion of urethra, 28L,
7 postoperative erosion of bladder, 28M,
8 postoperative erosion of vagina, 28N?

9 A. I know where they are.

10 MR. DAVIS: I'm just trying
11 to see the exhibit number.

12 MR. WALLACE: Just answer
13 the question.

14 I'm sorry. Does it say --
15 sorry. State it again. I think
16 he talked to her and sort of --

17 MR. DAVIS: Sorry.

18 MR. WALLACE: -- got me off
19 kilter and probably her, too.

20 BY MR. COMBS:

21 Q. The risk perforation by
22 mesh, my question is: In the risk
23 analysis at 28L, M, and N, is there the
24 risk set forth of erosion of urethra,

1 erosion of bladder, and erosion of
2 vagina?

3 A. Those hazards are listed.

4 Q. And include remediation of
5 information IFU in training?

6 A. Yes.

7 Q. And is the risk of infection
8 set forth in the risk analysis?

9 MR. WALLACE: Can you give
10 the Bates. I think it's 932;
11 right?

12 THE WITNESS: Did you say 9?

13 MR. WALLACE: 32.

14 MR. COMBS: 28D. It's page
15 937.

16 MR. WALLACE: Okay.

17 BY MR. COMBS:

18 Q. Does it set forth level of
19 wound infection and urinary tract
20 infection higher than for other
21 incontinence procedures?

22 A. I'm sorry. Was your
23 question is it listed as hazard?

24 Q. Yes.

1 A. Level of wound infection,
2 yes, it says it's not imaginable.

3 Q. Okay. And urethral tear, is
4 that listed in -- so at 28H, does it list
5 the risk of injury of urethra?

6 A. I'm trying to locate it.

7 Q. 28H on page 937.

8 A. Yes. Injury.

9 Q. For mesh broken and torn
10 mesh, is there analysis done -- on page
11 935, it's N19 -- of the tensile strength
12 elongation, bending stiffness, and pore
13 size of the mesh?

14 A. Those hazards are listed.

15 Q. For bent needle, at 13AG,
16 does it list, Needle curvature is not
17 required?

18 MR. WALLACE: Where you at?
19 Because you say bent needle,
20 but that's not in the document.

21 MR. COMBS: Bent needle.
22 And it says, Needle curvature is
23 not as required.

24 MR. WALLACE: Give us the

1 Bates, please.

2 MR. COMBS: 933. It's on
3 the second page of the document.

4 THE WITNESS: It says,
5 Needle curvature is not as
6 required.

7 BY MR. COMBS:

8 Q. And, for example, Dull
9 needle, two below that, Needle tip is not
10 as required (not as sharp as required).

11 Is that risk assessed in the
12 risk analysis?

13 A. The hazard is listed.

14 Q. Now, what were the
15 frequencies of these risks that are the
16 subject of this memorandum?

17 A. So the complaint analysis
18 has a list here.

19 THE WITNESS: I'm very
20 confused. He said memorandum. So
21 I'm assuming that --

22 What is it you mean when you
23 say "memorandum"?

24 BY MR. COMBS:

1 Q. I apologize if I called it
2 the wrong thing. I'm talking about the
3 document written by Ms. Meltzer.
4 Device --

5 A. Right. You're talking about
6 the document which says that these are
7 new risks, and they weren't in the DDSA.
8 Right. Yes.

9 Q. And we have just gone
10 through them, and --

11 A. Yes.

12 Q. -- they were, in fact, in
13 the risk analysis.

14 MR. WALLACE: Objection to
15 form. That's not her testimony.

16 BY MR. COMBS:

17 Q. These risks were in the risk
18 analysis, weren't they?

19 A. That is not what I said in
20 my report, because I used this.

21 Q. Ms. Wilson, but I'm not
22 asking that question now.

23 Here's the question I'm
24 asking.

1 The risks that are set
2 forth, those risks are set forth in the
3 risk analysis in 2001, aren't they?

4 MR. WALLACE: Same
5 objection. Objection to form.

6 THE WITNESS: You asked me
7 if the risks. I answered that the
8 hazards were listed.

9 BY MR. COMBS:

10 Q. Okay. Now, on Attachment 1
11 and 2 of that document, the occurrence
12 rates and frequencies are set forth of
13 the complaint review, aren't they?

14 A. There's two tables, and they
15 talk about -- I'm sorry. Say it again.

16 Q. The frequency of the
17 complaints for all of the risk categories
18 are covered on Attachment 1 and 2, aren't
19 they?

20 A. There's predicted and
21 actual. And I honestly am confused,
22 because this is talking about the
23 Preventia document, and it's confusing.

24 Q. I apologize.

1 A. Yes, the frequencies of
2 complaints are --

3 Q. I'm going to interrupt you
4 just because that's not what I'm asking.
5 So let me just ask the question again,
6 because I didn't do it -- obviously
7 didn't do a good job of asking it.

8 And then if you want to add
9 that answer after I ask the question
10 again, please feel free to do so.

11 What I was asking you about
12 was that this table just sets forth the
13 actual occurrence rate, that's what I was
14 asking you, for the complaint review.

15 A. So you're asking the actual
16 number of complaints.

17 Q. Yes, ma'am.

18 A. The actual numbers are
19 listed at the tables.

20 Q. And so, for example, for
21 vaginal extrusion, we're talking about a
22 reported -- a complaint rate of 1 in
23 18,000; right?

24 A. That's what it says, yes.

1 Q. And for urethral erosion,
2 we're talking about a complaint rate of 1
3 in 35,000?

4 A. Yes. There were six
5 occurrences.

6 Q. Perforation by mesh, we're
7 talking about a rate of 1 in 53,000?

8 A. Yes.

9 Q. Infection, we're talking
10 about a complaint rate of 1 in 213,000?

11 A. That's what it says.

12 Q. For vaginal incision, we're
13 talking about a complaint rate of 1 in
14 213,000?

15 A. Are we doing the same thing?
16 I'm just reading you the numbers in the
17 report? That's all you want me to do?

18 Q. Yes.

19 A. Okay.

20 Q. I mean, that's what we're
21 talking about in this complaint review.
22 We're talking about the number of
23 complaints.

24 A. I understand that. I just

1 want to make sure that's all you want me
2 to do is read what's on the page.

3 Q. Sure.

4 A. Okay.

5 Q. All right. So those are the
6 rates we're talking about.

7 And for broken mesh, talking
8 about 1 in 19,000, that's the complaint,
9 the actual occurrence rate?

10 A. I'm sorry.

11 Q. It's in Attachment 2.

12 MR. WALLACE: We can agree
13 that the document says what it
14 says.

15 MR. COMBS: Okay.

16 THE WITNESS: I guess my
17 whole thing, that even if the rate
18 is low, the injuries can be
19 severe.

20 I have worked in several
21 places where we have had very -- I
22 mean, three to five complaints,
23 but they're important. And we
24 stop everything. We do a task

1 force. We address them.

2 So just because the number
3 is low does not mean it's not
4 significant, I guess.

5 BY MR. COMBS:

6 Q. Ma'am, here's my next
7 question to you.

8 Are those occurrence rates
9 within the predicted occurrence rates in
10 the 2001 risk analysis, every one of
11 those?

12 A. Are you referring to this
13 document with a Bates number --

14 MR. DAVIS: Exhibit 13.

15 BY MR. COMBS:

16 Q. Yes, ma'am, Exhibit 13 in
17 your hand.

18 A. I don't see any predicted
19 occurrence numbers in this document.
20 Rare, frequent, probables aren't numbers.

21 Q. Ma'am, have you -- strike
22 that.

23 Is there a procedure that
24 sets forth what the definition is for

1 rare, for probability of occurrence?

2 A. I'm sure there is one that
3 gives a range. And we'd have to go
4 locate the one that was in effect on
5 August 5th, 2001, find out the range, and
6 then directly compare.

7 But this document says,
8 predicted versus actual, right here.

9 Q. And you haven't done that.
10 I mean, you haven't -- you have not
11 looked at whether --

12 A. What I did is I took this
13 document as an educated person, and that
14 this was factual, and I looked at this
15 document in extreme detail. And I
16 analyzed it, and I put it in my report.
17 And I did do that. I did every single
18 bit of that.

19 Q. Ma'am, here's the question I
20 ask you.

21 The question is: For the
22 risk analysis for 2001, did you calculate
23 for any of these that are set forth,
24 whether those were within the predicted

1 occurrence rate?

2 A. I did not go back and do it,
3 because this piece of document is
4 absolutely just terrible. It's not, in
5 my opinion, worth the paper it's written
6 on.

7 Q. And you didn't -- I'm sorry.

8 A. It's my opinion, and that's
9 why it's -- how it is, it says, Not
10 imaginable. What number is that? Not
11 imaginable. I have never seen that in 30
12 years of doing this type of document,
13 that someone would write, Well, I can't
14 imagine that.

15 Q. And do you know what
16 infection rates are for the other
17 procedures that it was compared to?

18 A. I know what -- how to find
19 out about infection rates. And it's very
20 specific to each procedures. And I don't
21 have that tabulated, no.

22 Q. And for none of the risks
23 that are set forth in the risk analysis
24 and none of the risks that are set forth

1 in the -- I apologize, I've forgotten the
2 exhibit number -- Exhibit 17, none of
3 those did you go back and check to see
4 whether they were within the estimated
5 probability of occurrence through the
6 risk analysis that was done in 2001.

7 MR. WALLACE: Objection to
8 form. Assumes facts not in
9 evidence.

10 THE WITNESS: This isn't
11 quantitative. You're trying to
12 ask me to compare qualitative to a
13 quantitative. Again, that's
14 apples to oranges.

15 BY MR. COMBS:

16 Q. No. This is probability of
17 occurrence.

18 A. Right. That's a range.
19 You're saying --

20 Q. Listen, I'll represent to
21 you that there's a frequency set forth in
22 the Ethicon procedures.

23 A. I understand that.

24 Q. Do you know what it is?

1 A. I can go look in the
2 procedures.

3 Q. You didn't do that. You
4 haven't done that.

5 A. I have looked in the
6 procedure. I have cited that procedure.
7 I even classified it. I said there's six
8 classifications used in that procedure,
9 which is -10.

10 Yes. I'm aware of that
11 procedure.

12 Q. But the procedure you're
13 talking about isn't even the procedure
14 that this risk analysis was done to.

15 A. Well, that's the procedure.
16 It doesn't say, does it? It doesn't seem
17 to be following anything.

18 Q. And did you ask your lawyers
19 to provide you with -- you've testified
20 that you reviewed this risk analysis
21 before today.

22 Did you ask anyone to
23 provide you with the procedures that
24 govern this risk analysis?

1 A. I have every procedure, to
2 my knowledge, regarding risk, and I asked
3 for all them.

4 Q. So if you don't have the
5 procedure that governs this risk
6 analysis, if you don't have it in your
7 files, then you didn't have one of the
8 things you wanted to do this review, did
9 you?

10 A. It is possible that
11 something was missed, and I'd be glad to
12 take a look at it.

13 Q. Sure. But if you don't have
14 this, if you don't have the procedure
15 that governs this risk analysis that's
16 one of the things you wanted in order to
17 do this review, isn't it?

18 A. You know, I said several
19 times, if there's something I overlooked
20 or there's some other documents, I'm sure
21 that, you know, in the thousands of pages
22 I could have overlooked it or,
23 furthermore, I would be glad to take a
24 look at it now.

1 MR. COMBS: Let's mark this
2 as 18.

3 - - -

4 (Whereupon, Exhibit Wilson
5 18 was marked for identification.)

6 - - -

7 BY MR. COMBS:

8 Q. Ms. Wilson, did you ever
9 look at the Surgeon's Resource Monograph
10 for TVT?

11 A. I'm not sure. I might have
12 seen this.

13 Q. If it's not on your reliance
14 list, does that mean that you didn't
15 review it?

16 A. If it's not on my reliance
17 list, then I didn't review it.

18 When it came to surgeons'
19 documents, so this is like Surgeon's
20 Monograph, it wouldn't have been one I
21 focused on, so it could have been buried
22 in there. If it wasn't on the list, then
23 I didn't look at it.

24 Q. Now, do you know whether

1 Ethicon was teaching surgeons about the
2 risks that are set forth in the DDSA
3 evaluation that you testified about two
4 years prior to that DDSA re-evaluation
5 being prepared?

6 A. I'm sorry. Was that a
7 question?

8 Q. Yes.

9 A. I'm sorry.

10 Q. Might have been a bad
11 question, but it was a question.

12 Do you know what the
13 monograph is?

14 A. Was this on my list? I
15 don't know.

16 Q. I do not believe it was on
17 your list. I could be wrong.

18 A. I don't remember seeing
19 this. I said it could have been, and if
20 I did see it --

21 Q. Ms. Wilson, look, I'm not
22 trying to trip you up whether it was or
23 wasn't on the list. If I'm wrong, I'm
24 wrong.

1 A. I don't remember seeing this
2 pretty picture, but I told you several
3 times, I can't remember every document I
4 looked at.

5 It's not cited in my report.

6 Q. Let's must move past whether
7 it is or isn't in the reliance list and
8 let's ask some questions about it.

9 Now, do you know whether
10 Ethicon was training surgeons in the risk
11 of this procedure years before the DDSA
12 re-evaluation came out?

13 Do you know that?

14 That's the question.

15 A. I can't state whether
16 Ethicon was doing it at what time or not.

17 I can tell you that most
18 medical device companies have clinical
19 experts that go out and train their
20 surgeons. And that's very, very common
21 and expected in the medical device
22 industry.

23 Q. And the risks -- let's look
24 at some of the risks that you discuss in

1 your report from the DDSA re-evaluation.

2 So, for example, vaginal
3 extrusion, do you know whether Ethicon
4 was teaching that risk to surgeons?

5 A. Are you looking at somewhere
6 on my report?

7 Q. I'm looking at page 9, mesh
8 protrusions.

9 A. Here's what I know. I don't
10 remember looking at this. I'm not a
11 clinician and I'm not a doctor.

12 Q. Okay.

13 A. So do I know if they were
14 doing it and at what time? No, I do not.

15 I know it's common in the
16 industry. And whatever they said they
17 did in here, all I'm going to do is
18 assume.

19 Q. So --

20 MR. WALLACE: You're asking
21 her to guess.

22 THE WITNESS: Yeah. You're
23 asking me to guess, and I can't
24 guess.

1 BY MR. COMBS:

2 Q. Well --

3 A. I have not seen this. I
4 have no facts presented to me to know,
5 yes or no.

6 Q. So when you're discussing in
7 your report what you describe as new
8 hazards --

9 A. New hazards from my report
10 directly from this document as stated.

11 Q. Okay. And so you just took
12 that out of that document.

13 And did you do anything to
14 confirm whether they were or were not --

15 A. I did.

16 Q. -- new hazards?

17 A. I went back to the Preventia
18 report, which was the reference for this.
19 It clearly refers to that, and I compared
20 that.

21 And so I did do that, yes.

22 Q. And did you make any efforts
23 to determine whether that's a mistake,
24 whether they are not new hazards?

1 A. What I did look at -- you
2 can't have the complaint; right? They
3 didn't have the complaints, the design;
4 right?

5 So these -- I just said I
6 did.

7 Sorry. I don't know what
8 I'm saying anymore.

9 Q. So would you agree with me
10 that two years before that DDSA
11 re-evaluation was written, Ethicon is
12 teaching about the risks that in your
13 report you're describing as new?

14 A. No. I have no knowledge if
15 they're teaching, if that just is
16 printed, if they used it, if it was -- I
17 have no knowledge.

18 Q. Did you do any investigation
19 to determine that?

20 A. That was not in the scope of
21 my report is what they taught the
22 clinicians.

23 I'm talking about the risk
24 management process and design control

1 process.

2 Q. And in the risk analysis, do
3 they talk about one way to remediate the
4 risk is through surgeon training?

5 A. They talk about IFU -- is
6 this the right document?

7 Training. So the IFU could
8 be training. There's many ways of doing
9 training.

10 I have no knowledge of what
11 they did in training.

12 Q. You don't know what was done
13 to remediate the risks through training,
14 do you?

15 A. No. I think I said that
16 three or four times. That was not on my
17 list. I didn't look at that document.

18 MR. WALLACE: Are we coming
19 up on a break?

20 MR. COMBS: We can break, if
21 you want.

22 MR. WALLACE: Let's take a
23 couple of minutes.

24 - - -

1 (Whereupon, a brief recess
2 was taken from 4:40 p.m. to 4:48
3 p.m.)

4 - - -

5 (Whereupon, Exhibit Wilson
6 19 was marked for identification.)

7 - - -

8 BY MR. COMBS:

9 Q. Ms. Wilson, I want to ask
10 you some questions now about the 2006
11 complaint review --

12 A. Okay.

13 Q. -- that you discuss at pages
14 13 and 14 of your report.

15 Now, we talked about the
16 2002 complaint review, and we'll talked
17 about the 2006 complaint review.

18 Were there any other
19 complaint reviews that you reviewed?

20 A. Not that I recall seeing.

21 Q. Now, for this complaint
22 review that we'll discuss -- and I have
23 handed you what's been marked as
24 Exhibit 19. And it's Technical File

1 Amendment for Laser Cut Mesh product
2 Code.

3 Did you review this
4 document?

5 A. This top one for laser cut?

6 Q. Yes, ma'am.

7 A. No. If it said laser cut, I
8 just put it aside.

9 Q. All right. And if you go
10 into the document -- strike that.

11 In your report, you identify
12 five complaint categories: Mesh
13 fraying/roping, sheath damage, erosion,
14 exposure, and pain.

15 Do you remember that?

16 A. I do.

17 Q. Now, were any of those
18 complaint categories new?

19 A. These complaint categories
20 were delineated. These were, I believe,
21 I talked about in my report and
22 referenced each one individually and
23 talked about how they were known.

24 So, to my knowledge, they

1 weren't new.

2 Q. And for the five categories
3 that you discussed, were all five of
4 those complaints within the estimated
5 frequency that had been set forth in the
6 risk analysis plan?

7 A. In the risk analysis plan?

8 Q. Yes, ma'am.

9 A. Where is that document?
10 The legacy risk analysis
11 plan?

12 Q. Yes, ma'am.

13 A. I do know that exists. Let
14 me -- is that in the stack?

15 I know I looked at it, but
16 I'm wondering if it's in the stack or
17 not.

18 Q. As we sit here right now, do
19 you have any information at all that
20 these five categories that you discuss in
21 your report, that the actual occurrence
22 rate exceeded the estimated occurrence
23 rate?

24 A. I can tell you that they

1 were either low or moderate. I can't
2 remember exactly what they were predicted
3 to be. I don't remember seeing a
4 prediction by failure mode. I just don't
5 remember ever seeing that document.

6 Q. As we sit here right now,
7 you don't have any information that they
8 would be above an estimated frequency?

9 A. I can't looking at failure
10 mode and say I expect this to be
11 moderate. I just don't know that.

12 Q. Each one of these risk
13 categories -- strike that.

14 Each one of these complaint
15 categories, it had been discussed in a
16 prior risk analysis, hadn't it?

17 A. A prior risk analysis?

18 Q. Yes.

19 A. I'm just trying to make sure
20 I understand your question.

21 Q. Okay.

22 A. It's getting late in the
23 day. I'm sorry.

24 Q. Just if you know was

1 prepared in February 23rd --

2 A. 2006.

3 Q. Okay.

4 A. This is sort of going back,
5 and this was for a period of time. So
6 this says -- let me read it.

7 The base was from 2003 to
8 2006. So it was a four-year period.

9 And you are asking me again?

10 Q. I'm asking you if each one
11 of these complaint categories had been
12 identified in a prior risk analysis.

13 A. There's only two. So I
14 don't. I would have to go back and look
15 at the --

16 MR. WALLACE: If you know.

17 THE WITNESS: -- specific
18 ones.

19 MR. WALLACE: You either
20 know or you don't.

21 THE WITNESS: I just don't
22 know. I don't know right off the
23 top of my head. I would have to
24 go look.

1 BY MR. COMBS:

2 Q. Had Ethicon done CAPAs for
3 any of these complaint categories?

4 A. I think I talked about
5 CAPAs. I don't think there was any CAPA
6 for those complaint categories.

7 We talked about CAPAs. And
8 in my report I talked about one CAPA, and
9 that was relating to missing documents.

10 So I don't know of any
11 CAPAs, no.

12 Q. So as we sit here right now,
13 you don't know of any CAPAs that relate
14 to any of these five complaint
15 categories.

16 A. No. I don't know of them.

17 Q. Do you agree with me that
18 the purpose of the complaint review that
19 Mr. Lamont did was in order to predict
20 potential risks for laser cut mesh?

21 A. There's a variety of reasons
22 that you do complaint reviews. That may
23 be one of them. But first off, you are
24 required to do periodic trending and look

1 at your complaints, analyze your
2 frequency of complaints.

3 And you do need to feedback
4 new things into your risk management
5 process and for new product development.

6 So there's a variety of
7 reasons you would do that.

8 Q. Okay. But I'm asking about
9 this complaint review, this complaint
10 review done by Mr. Lamont.

11 A. I can't say why Ethicon
12 specifically did this for new products.
13 I can't speak to what their intent was
14 for their new products.

15 I do know that it's required
16 to do for existing products. And that's
17 part of why they did it.

18 Q. But you don't know why this
19 complaint review was performed.

20 A. It had been four years since
21 they looked at the TVT, so it's to
22 satisfy the requirements for complaint
23 review.

24 So -- and it's in the their

1 procedure, so that's why it was done in
2 my estimation.

3 If there were other motives,
4 I'm not knowledgeable of those.

5 Q. And the hazards and harms
6 that are set forth in the Risk Management
7 Report, 17, are the hazards and harms
8 that were being reviewed in preparation
9 for the introduction of laser cut mesh,
10 weren't they?

11 A. I specifically stated, I was
12 not reviewing laser cut, so I can't speak
13 to that.

14 Q. You don't know --

15 A. I analyzed this section that
16 was the TVT base. And that was what I
17 looked at.

18 Q. And you don't know what the
19 hazard and harms that were generated from
20 Mr. Lamont's review of this complaint
21 review, you don't know what they were
22 used for.

23 A. Well, I mean, I read the
24 analysis, but I don't know if there were

1 other uses for it or anything like that.
2 I don't know what Ethicon's thought
3 processes were other than what's stated.

4 Q. Following this complaint
5 review that was performed in 2006 --

6 A. May I get another water?

7 Q. Yes, ma'am.

8 A. Thank you.

9 Q. Following this complaint
10 review in 2006, has Ethicon performed any
11 clinical expert reports or clinical
12 evaluation reports?

13 A. On which products?

14 Q. On TVT.

15 A. TVT mechanically cut mesh?

16 Q. Yes, ma'am.

17 A. I don't know. I know that
18 there were some -- couple of them in the
19 documents, but when it went to clinical,
20 I really didn't focus in on whether they
21 did that after 2006 or not.

22 Q. And is a clinical evaluation
23 one form of risk analysis?

24 A. That may be an input or an

1 output. But that in and of itself is not
2 a risk analysis.

3 Q. Is one of the things that's
4 being done in a clinical expert report to
5 make a determination about whether the
6 product's risks out way its benefits?

7 A. I don't know. I would have
8 to look at the document. There's so many
9 variations of those things.

10 Q. And as we sit here today,
11 you haven't looked at any of the clinical
12 expert reports that came after this --

13 A. I don't know --

14 Q. -- complaint.

15 A. -- that to be true or not.

16 I know that I did look at a
17 couple. I don't know what the timing
18 were. I would have to go back to my
19 documents.

20 Or show me the ones that
21 were in my list and I'll be glad to --

22 Q. Do you have any opinions
23 regarding any of the clinical expert
24 reports performed after this complaint?

1 A. I don't even know what the
2 timing was. I'm sorry.

3 Q. Is it fair to say, as we sit
4 here today, you don't have any opinions
5 regarding the clinical expert report
6 prepared after this complaint analysis
7 was done?

8 A. I don't think that's fair,
9 no. I think it's fair to say I don't
10 know if they exist.

11 Q. Okay.

12 A. And I don't know if they
13 exist on the product, which is the scope
14 of my report.

15 Q. You don't know whether there
16 had been any clinical expert reports
17 after 2006 that addressed TVT.

18 A. TVT mechanically cut, TVT-R
19 mechanically cut.

20 I don't want to mix
21 procedures. I don't want to mix
22 processes. So I just don't know.

23 Q. Don't know.

24 One of the opinions that you

1 had was that for risk analysis purposes,
2 TVT and TVT-O can't be grouped; is that
3 correct?

4 A. Absolutely.

5 Q. What's the indication for
6 use for TVT?

7 A. TVT is used for stress
8 urinary incontinence.

9 Q. What is the indication for
10 just for TVT-O?

11 A. That's not the basis of what
12 my opinion is based on.

13 Q. My question --

14 A. I'd have the look at TVT-O
15 and find that out.

16 Q. What is the indication for
17 use for TVT-O?

18 A. I would have to go
19 double-check that. I believe it's for
20 stress urinary incontinence, too. It's a
21 different surgical technique and
22 different tools accessories.

23 Q. They have the same
24 indication for use, don't they?

1 A. Sure. That has no bearing
2 on why I think they combine. They cannot
3 become be combined just because of that
4 one little detail.

5 Q. Ms. Wilson, could you
6 hand --

7 A. That one?

8 Q. Yes. Thank you.

9 Now, what's the procedure
10 that Ethicon used when it was making the
11 decision about whether TVT-O and TVT
12 should be grouped together in a risk
13 manager legacy report?

14 A. In the plan they made a
15 statement.

16 Is the plan in here?

17 Q. Your right hand is on top of
18 it.

19 A. That's the report.

20 Q. Okay.

21 A. I'm trying to find the plan.
22 Because there were a couple of versions,
23 and I believe they talked about that in
24 the plan.

1 Q. Ms. Wilson, let me try a
2 different question then.

3 Who were the Ethicon
4 employees that were involved in the
5 decision for the risk management report?

6 A. Looks like there was a
7 project manager, a director of risk
8 management, a medical director, an
9 engineering fellow, and a quality --
10 worldwide quality engineering manager.

11 Q. So quality engineer, that's
12 what you do; right?

13 A. That's one of the elements I
14 have done for 30 years. That is...

15 Q. I mean, that's what you do.
16 That's what you are. You're a quality
17 engineer.

18 MR. WALLACE: She's
19 answered. Objection to form.

20 MR. COMBS: Okay.

21 BY MR. COMBS:

22 Q. Now, in addition to a
23 quality engineer being in this team,
24 there was also a director of risk

1 management, wasn't there?

2 A. I believe I have stated all
3 of those people on that form.

4 Q. There's a medical director?

5 A. I have stated that there is
6 a senior project manager, a director, WW
7 risk management, medical director,
8 engineering fellow, RND, WW quality
9 engineering manager.

10 Q. So at least five people
11 participated in developing the risk
12 management report, TVT and TVT-O, didn't
13 they?

14 A. That's what this says.

15 Q. All right. What are the
16 qualifications of Dr. Robinson, the
17 medical director?

18 A. I have --

19 Q. Do you know anything about
20 him?

21 A. I don't know. I haven't
22 read his CV, no.

23 Q. Do you know how many of
24 these procedures he's performed?

1 A. I could not tell you that.

2 Q. If I ask you to assume that
3 Dr. Robinson is a urogynecologist, would
4 Dr. Robinson be in a better position than
5 you to judge the clinical risks of these
6 procedures?

7 MR. WALLACE: Objection to
8 form.

9 THE WITNESS: As far as the
10 clinical, sure.

11 BY MR. COMBS:

12 Q. Yes, ma'am. I mean --

13 A. He may be. That has nothing
14 to do with the risk management process
15 and whether to do with combining or not
16 combining the different products, which
17 is the original question you asked me.

18 Q. You disagree with their
19 decision to combine the two for risk
20 purposes.

21 A. It's not that I disagree.
22 It's stated in the standards, and it's
23 accepted throughout the industry that you
24 have to look at each thing individually

1 for its application in its placement, and
2 not just for convenience sake.

3 Q. And what specific standard
4 are you referring to?

5 A. I'd be glad to show you. It
6 was the one I pointed out, the very first
7 box this morning.

8 We started with the 2000
9 version.

10 We start by looking -- oh, I
11 know exactly what you're going to try to
12 catch me on.

13 You go to the Section 4.2.

14 So what it says is, you look
15 at Intended Use. That's one of the
16 items. Then you go to 4.2.

17 Q. I apologize. I just need
18 you to say on the record what it is you
19 are referring to.

20 A. I'm referring to ISO 14971,
21 Risk Management -- Medical Devices,
22 Application of Risk Management to Medical
23 Devices.

24 MR. DAVIS: Which version?

1 THE WITNESS: This is the
2 2007, but I would be glad to look
3 at the 2000 version, because I
4 think we're talking about 2006,
5 right?

6 BY MR. COMBS:

7 Q. Yes, ma'am.

8 A. Let's go to the right one
9 here, the right version.

10 Here, this is the one we
11 were looking at this morning. It's the
12 ISO 14971, same title, 2000 version.

13 Do you want me to repeat the
14 title?

15 Q. Medical Devices -
16 Application of Risk Management to Medical
17 Devices.

18 Okay. And what's the
19 specific standard that you are saying
20 precludes these from --

21 A. What I'm saying is that you
22 need right here and throughout this
23 document, it's not one phrase you're
24 going to find it, it's the intent of this

1 document.

2 It says, you need to look at
3 the use, the purpose, hazards, risks.

4 Part of that is looking at where it ends
5 up in the woman's body, the surgical
6 techniques, and things such as that, the
7 different system interfaces, not the same
8 materials, different processes of the
9 manufacturing.

10 So you can't mix one thing
11 with another.

12 Q. What you're pointing to is
13 Figure 1?

14 A. It's also in figure -- which
15 is also in my report, a little more
16 detail. It's in Figure 2, if you would
17 like to look at that.

18 Q. And what is -- what are the
19 different risks of TVT-O and TVT?

20 A. Well, we have established --
21 or, to me, is that one uses a
22 different -- they use different
23 instrumentation. They use different
24 surgical techniques. And I believe they

1 end up in different places in the woman's
2 body.

3 Even though they use the
4 same base mesh, you can't say that apples
5 compare -- again, the apples and oranges,
6 in my opinion.

7 Q. And my question was: What
8 are the different risks?

9 A. I didn't look at the TVT-O
10 risk management and compare that to those
11 in the TVT-R. So --

12 Q. You don't know -- I'm sorry
13 to --

14 A. I do --

15 Q. -- interrupt.

16 A. -- need -- in order to
17 answer that question, I would have to go
18 look at the differences in the TVT-O.

19 So you're asking me a
20 question that I would have to guess on.

21 Q. And I'm asking you a
22 question that to date you haven't done.

23 A. I wasn't asked to look at
24 TVT-O, no.

1 Q. So you have not made --

2 A. Absolutely not.

3 Q. And, I'm sorry, I started to
4 interrupt you.

5 Are you finished?

6 A. (Gesturing.)

7 Q. Are you finished?

8 A. I am now.

9 Q. As we sit here today, you
10 haven't assessed the risk for TVT-O, have
11 you?

12 A. No.

13 Q. What are the different risks
14 presented by machine cut and laser cut
15 mesh?

16 MR. WALLACE: And what?
17 Laser cut?

18 MR. COMBS: Yes.

19 MR. WALLACE: Hasn't the
20 judge limited to this trial, this
21 is a TVT mechanical cut report.

22 And she's already told you
23 about 50 times she hasn't looked
24 at laser cut.

1 And we're getting -- just so
2 you understand, I have questions
3 for her and you're going to miss
4 your plane if you keep doing this.

5 MR. COMBS: That's okay.

6 MR. WALLACE: I think you're
7 intentionally doing it at this
8 point.

9 You're going off on a
10 territory that has absolutely --
11 you know that this a TVT
12 mechanical cut report, and
13 you're -- frankly, she's told you
14 the 50 times today what she looked
15 at what she didn't look at. And
16 you know that to be the case.

17 BY MR. COMBS:

18 Q. Ms. Wilson, do you or do you
19 not have the opinion set forth on page 14
20 of your report that it was improper to
21 group mechanically cut and laser cut mesh
22 for purposes of risk analysis?

23 A. That is my opinion. And I
24 just stated why. You cannot mix apples

1 with oranges when it comes to risk.

2 Q. Now, after the big speech by
3 Mr. Wallace that I'm asking about a
4 question that's not in your report,
5 that's something that's in your report.

6 A. I did not look at the risks
7 associated with laser cut mesh. I
8 excluded that.

9 I do believe that you cannot
10 mix different manufacturing processes,
11 different surgical techniques, different
12 products together for the purposes of
13 risk management. And that's what I
14 stated in my report.

15 Q. As we sit here today, you
16 have not analyzed what the risks are of
17 laser cut mesh, have you?

18 A. That's irrelevant to my
19 opinion stated on page whatever it was.

20 Q. Ms. Wilson, as we sit here
21 today, have you assessed the risk of
22 laser cut mesh?

23 A. I have not assessed -- I
24 have assessed that they are different

1 products and therefore cannot be grouped.

2 Q. Have you assessed the risk
3 of laser cut mesh?

4 A. No. I have answered that at
5 least 20 times today. I did not look at
6 the laser cut mesh risk in and of itself.

7 Q. Now, Ms. Wilson do you know
8 whether the risk management report that
9 you have opined upon, whether that was
10 included in the technical file that was
11 reviewed by BSI?

12 A. By who?

13 Q. BSI?

14 A. I'm trying to remember. I
15 believe it was, but I'm not a hundred
16 percent sure.

17 I really do believe it would
18 be in there, because that should be in
19 the technical file.

20 Q. Now --

21 A. But, please, I'm not a
22 hundred percent sure. I just think I saw
23 it in there. It makes sense.

24 Q. Now, in your report, you

1 also have the opinion that it was
2 improper to group TVT-Exact and TVT
3 together.

4 That's on page 14 of your
5 report.

6 A. Thank you.

7 Yes. That's the same
8 answer.

9 Q. Okay. Now, what are the
10 different risks presented by TVT-Exact?

11 A. I just answered that I
12 didn't analyze the risks associated with
13 different products.

14 What I said is, is that you
15 can't combine them because of how the
16 standards are and based on my many years
17 of experience doing this.

18 For example, I have done it
19 for four versions of shoulders, seven
20 different versions of knees, and you
21 don't just combine and mix them and
22 match. You have to look at each one
23 specifically.

24 Q. Are you finished?

1 MR. WALLACE: I think that's
2 a little flippant the way you're
3 doing that.

4 MR. COMBS: I'm not. Let's
5 go off the record.

6 - - -

7 (Whereupon, a discussion was
8 held off the record.)

9 - - -

10 BY MR. COMBS:

11 Q. Now, in the document that
12 you're referring to about the grouping of
13 TVT and TVT-Exact, what was that
14 document?

15 A. I've said three or four
16 times, I believe it's the risk plan,
17 there were two or three versions.

18 There was a legacy risk
19 management plan that listed all the
20 different devices that were going to be
21 re-evaluated. There were two conditions
22 by which the product got on that risk
23 management legacy plan.

24 I just don't have that in

1 front of me as we sit here today.

2 Q. Okay. So you think that the
3 grouping of TVT-Exact and TVT was part of
4 a legacy plan?

5 A. I think that there was a
6 large list of documents. And it was the
7 plan that goes with this Risk Management
8 Report 44.

9 There was an RMP that goes
10 with that. To the best of my knowledge,
11 that's what called out which products
12 were on that.

13 Q. And I may be wrong about
14 this. It's my belief that what you were
15 referencing in Exhibit 56 was a technical
16 file for TVT-Exact. I could be wrong.
17 That was my understanding.

18 A. It may -- I think that I may
19 have misunderstood your question.

20 The document -- could we
21 just look at that risk management plan?
22 Because I think that's the one that calls
23 out the grouping of the reports, which is
24 what I thought you asked me about.

1 Q. This is what was produced to
2 me as being the document that was
3 Footnote 56 in your report.

4 A. That's not the document that
5 goes with this management report, which
6 is --

7 Q. Okay.

8 A. Do you want to repeat your
9 question again? It was why -- what to do
10 with -- it had to do with this report and
11 why they grouped these products together?

12 Q. Yes. And, ma'am --

13 A. And there was a plan and it
14 specified exactly why.

15 Q. And I had -- and, again, I
16 don't think there's any controversy on
17 this.

18 TVT-Exact didn't even exist
19 at the time that this report was written.

20 A. And I'm sure that I may have
21 looked at that, too. If it had to do
22 with the fact that they were different
23 products, I may have been making that
24 point.

1 But that's not what you --
2 let's go back to what you asked, please.

3 Q. Here's what I asked you.
4 And what I asked you was: What was the
5 document that grouped TVT and TVT-Exact?

6 And it's my understanding
7 from Footnote 56 that what you're
8 referring to is this document, the CE
9 mark technical file for Gynecare TVT
10 retropubic devices.

11 A. If you look at the paragraph
12 above that in my report, and you look at
13 Footnote 52, that's what I believe
14 grouped these devices in the risk
15 management report.

16 Q. So it's your belief that
17 TVT-Exact is grouped in this risk
18 management report?

19 A. Okay. The risk management
20 plan called out for a host of documents,
21 a host of products to be reviewed.

22 Here's some of their catalog
23 numbers. Right. I don't have the
24 catalog numbers together, but I do know

1 that TVT is included in here.

2 So let's go through what I
3 said.

4 There was a risk -- if you
5 look at page 14, A final risk management
6 plan and associated report analysis of
7 legacy devices, that's Footnote 52,
8 products TVT and TVT-O were conducted.

9 Q. No.

10 A. And they were grouped.

11 Q. But that's not what I'm
12 asking now. I'm asking about TVT-Exact
13 and TVT.

14 In the bottom paragraph of
15 you say --

16 A. I said that they tried to
17 incorporate Ethicon products with laser
18 cut mesh. So some of these are laser cut
19 mesh.

20 Q. All right. And in that
21 paragraph you state, For example, the
22 2010 TVT technical file combines risk
23 analysis for the original TVT with
24 TVT-Exact; right?

1 A. And it probably does.

2 Q. Okay. Now, here's the
3 question that I wanted to ask you about
4 that.

5 I want to make sure the
6 record is clear. The technical file that
7 you're referring to, that's a technical
8 file used by European regulators, isn't
9 it?

10 A. We have gone through this at
11 least 20 times.

12 Technical files are used by
13 European regulators, and they are used to
14 evaluate quality systems and get CE mark.
15 They're very specific.

16 Q. Exactly. And that's this
17 document that you're referring to.

18 A. Many of those same documents
19 are used for many purposes. They're not
20 just single-purpose documents. Risk
21 management is one of those documents that
22 serves many purposes.

23 Q. And what you're specifically
24 referring to -- what your report says is,

1 for example, the 2010 TVT technical file
2 combines risk analysis for the original
3 TVT retropubic mechanical cut device
4 along with TVT-Exact.

5 That's what you're referring
6 to.

7 A. That is an example. I
8 believe there are many examples of those
9 things.

10 Yes. That is an example.

11 Q. Ms. Wilson, on page 14 of
12 your report, you talk about the grouping
13 of mechanical and laser cut mesh. And
14 you have seven footnotes that relate to
15 that.

16 A. On page what? Oh, down
17 here?

18 Q. Yeah. I'm talking about --

19 A. Okay.

20 Q. -- pages 14 and it carries
21 over into 15.

22 You have a section in your
23 report that deals with laser cut mesh.

24 And in that, you have -- you

1 reference seven footnotes -- six, I'm
2 sorry, six footnotes, from 57 through 62.

3 Are there any other
4 documents that you are relying on, other
5 than the documents in those footnotes,
6 for your opinion that laser cut mesh and
7 mechanically cut mesh present different
8 risks?

9 A. No. I considered so many
10 documents. I considered and went back
11 and looked at documents and documents and
12 documents.

13 These are the ones I quoted.
14 So I'm sure I considered many of them,
15 and these are the ones I footnoted
16 because I specifically called them out.

17 Q. Who selected the documents
18 that you footnoted?

19 A. I selected every document
20 that I wrote in this report.

21 Q. Are there any documents that
22 you were provided that relate to the
23 risks of laser cut mesh that you chose
24 not to include in your report?

1 A. There may well have been,
2 because I wasn't looking at the risks
3 associated with laser cut mesh. I was
4 looking at TVT mechanically cut for the
5 TVT-R.

6 So I was not analyzing laser
7 cut mesh. So I'm sure that I did not
8 include or reference many of those
9 documents.

10 Q. There's a clinical expert
11 report related to laser cut mesh that
12 analyzes whether the risks of laser cut
13 mesh and machine cut mesh are different,
14 isn't there?

15 A. You know, I just couldn't
16 tell you, as I sit here today, whether
17 there is or isn't.

18 Q. So as we sit here today, you
19 don't know whether there is a clinical
20 expert report that analyzes the risks of
21 laser cut versus machine --

22 A. I can't remember, because I
23 really wasn't focusing, again, on laser
24 cut mesh.

1 If it was cited here as a
2 footnote, I'm sure that if I relied on
3 it, if I -- for the footnote, I would
4 have footnoted it.

5 Q. In the last sentence -- last
6 full sentence on page 14, you say,
7 Similarly, the April 18th, 2006 clinical
8 expert report for Ethicon's laser cut
9 mesh noted that laser cut mesh is less
10 susceptible to particle loss compared to
11 the mechanical cut mesh.

12 A. Well, voila. I cited it and
13 it's been footnoted. Just like I said,
14 if I relied on it, I would have footnoted
15 it.

16 Q. Now, are there other
17 conclusions reached in that clinical
18 expert report that you have chosen to
19 ignore?

20 A. If you showed it to me, I
21 would have to review it. I can't
22 remember every word on every page.

23 Q. Sure.

24 Do you remember that the

1 assessment reached by -- strike that.

2 Do you remember that the
3 assessment made in the clinical expert
4 report is that the risks aren't
5 different?

6 A. I don't remember the wording
7 of everything. If you give it to me
8 again, I'll be glad to take a look. I
9 know I looked at it. I cited it.

10 Q. Ms. Wilson, on page 17 of
11 your report, you have five risks that you
12 describe as critical risks ignored by
13 Ethicon.

14 MR. WALLACE: There is no
15 question pending.

16 BY MR. COMBS:

17 Q. Yeah, have you gotten to
18 that? Did you find it? Are you on
19 page 17?

20 MR. WALLACE: She is.

21 MR. COMBS: Okay. Thank
22 you.

23 BY MR. COMBS:

24 Q. Now, who selected those five

1 risks? Did you select those or did
2 counsel select them?

3 A. You know, we talked about
4 the risks, and I reviewed the complaints.
5 And those are some of those that were on
6 that complaint report. In fact, many of
7 them were.

8 Q. I'm sorry. Did you finish?

9 A. Right. So I looked at the
10 documents, and I -- I'm sure I talked to
11 counsel also.

12 Q. Now, for each one of these
13 five risks that you set forth, I want you
14 to tell me what standard you believe was
15 violated by Ethicon's design control and
16 risk management process in regard to
17 these risks.

18 A. Okay. In general,
19 management has the responsibility in
20 ISO 13485, and there is also guidance
21 documents that -- international documents.

22 So there's a plethora of
23 documentation and also good quality
24 practices.

1 But if you need me to cite a
2 specific standard, it would be ISO 13485
3 and ISO 14971.

4 Those would be the two most
5 relevant standards that say that
6 executive management has a responsibility
7 to, one, consistently evaluate, through
8 management review, their processes,
9 products, complaints -- and we could look
10 at the standards if you choose -- and to
11 make sure that they have, you know,
12 sufficient systems in place, that they're
13 established, meaning they're written, and
14 effective, and that they maintain those
15 systems.

16 So those would be the
17 standards.

18 Q. For the risks that you set
19 forth on page 17, are you relying on any
20 medical literature to support your
21 opinion in regard to any of those risks?

22 A. Any medical opinion?

23 Q. Any medical literature.

24 A. Does that mean scientific

1 literature?

2 Q. Well, let's start with --

3 A. Published literature?

4 Q. Let's start with medical
5 literature.

6 A. Internal documents?

7 Q. Let's start with, are there
8 any peer-reviewed articles from medical
9 journals that you're relying on to
10 support your opinions regarding any of
11 those five categories?

12 A. Yes, I believe so.

13 Q. What are they?

14 A. If you look at Footnote
15 Number 75, for example.

16 Q. And that's Celine, Mary
17 article?

18 A. Yeah.

19 Q. Any other scientific or
20 medical literature that you're relying on
21 to support those five categories?

22 A. All of the canine studies
23 were scientific studies, they had
24 scientific data.

1 Let me keep looking.

2 I looked at medical director
3 testimony.

4 Is that scientific?

5 I'm just not sure where
6 you're drawing the line there. If it's
7 only peer-reviewed published, then I
8 believe that the one we just called up is
9 the only peer-reviewed published.

10 Q. Okay.

11 A. There may be some more.
12 Maybe 109, I can't be sure on that one.

13 Q. Maybe 108?

14 A. Oh, yeah, 100 eight. Excuse
15 me. I had my finger on 108.

16 Q. So the two articles that you
17 recall relying on would be the Mary
18 article in Footnote 75 and the Klinge
19 article in Footnote 108.

20 A. Those were the two that I
21 footnoted.

22 Q. Are there any other
23 published clinical or scientific
24 literature that you're relying on in

1 support of these opinions?

2 And when I say "these
3 opinions," I'm talking about the five
4 risk categories on page 17.

5 A. There may have been other
6 documents that I considered.

7 It's the same answer.

8 If I relied on them in these
9 exact sentences, I would have footnoted
10 them.

11 Q. Okay. Now, in regard to the
12 first risk category that you call out,
13 degradation, what is your definition of
14 degradation?

15 A. You know, I did look that up
16 and I wrote it down.

17 It's basically it breaks
18 down over time.

19 Q. In the second paragraph in
20 1, you have a statement, and I just want
21 to make sure that that is what you're
22 referring to.

23 It's evident that material
24 degradation was not considered as a

1 hazard which, over time, could lead to
2 mesh embrittlement, cracking, and
3 mechanical strength within the patient.

4 Is that what you're
5 referring to?

6 A. When I looked at the
7 documents, the application FMEA, which is
8 what was the document at the time that
9 this was designed, that's what I'm
10 referring to.

11 It wasn't considered in that
12 document.

13 Q. Okay. Is that the
14 definition of degradation that you're
15 using, could lead to mesh embrittlement,
16 cracking, and loss of mechanical
17 strength?

18 A. No. I just told you the
19 definition.

20 Do you want to read that
21 back?

22 It's when something breaks
23 down over time. So those could be
24 effects of degradation.

1 Q. So the definition you're
2 using for purposes of this report is that
3 it breaks down over time.

4 A. That's not the official
5 definition, but that's a paraphrase of
6 the definition.

7 Q. Do you know whether the
8 plaintiffs' experts in this case take the
9 position that degradation affects the
10 tensile strength of the mesh?

11 Do you know that?

12 MR. WALLACE: Do you know?

13 That's the only question?

14 MR. COMBS: Yes.

15 MR. WALLACE: If you don't
16 know, you don't know.

17 THE WITNESS: I can't
18 remember. I don't know. I might
19 have read that at one time. I
20 just can't recall.

21 BY MR. COMBS:

22 Q. Do you have any evidence
23 that would support that Prolene mesh
24 decreases in molecular weight or loses

1 tensile strength after implantation?

2 A. There was these animal
3 studies cited, and they had quite a bit
4 information on the breakdown of --
5 they're all marked in here.

6 Let's make sure. I want to
7 make sure I get this right.

8 I do talk about the animal
9 studies. I'm afraid I'm just at the end
10 of the day and I might get something
11 messed up here.

12 Because it was a series
13 here, they are right here under
14 degradation, and they were very explicit.

15 They were documented. It's
16 Footnote 76, 77, and 78.

17 And it had specific -- I
18 don't know if they were SEM analyses with
19 them that shows the breakdown in an
20 oxidated fashion.

21 Q. Do any of the studies that
22 you reviewed show that Prolene mesh or
23 Prolene sutures lose tensile strength or
24 lose molecular weight?

1 A. I can't recall. I know I
2 footnoted these. I would have to go back
3 and read these articles, because it
4 showed degradation.

5 Q. And your definition of
6 degradation is it breaks down over time?

7 A. I said that was a
8 paraphrase. I would go back to these
9 references that I footnoted.

10 Q. Okay. I mean, I'm not
11 trying to be difficult here. I mean,
12 you're talking about degradation. I just
13 want to know how you defined it.

14 A. I've answered it twice.

15 MR. WALLACE: You've asked
16 it, she's told you.

17 BY MR. COMBS:

18 Q. You've answered it once and
19 then told me that I was trying -- never
20 mind. I don't want to quibble about it.

21 Now, are you -- is it your
22 position that degradation can cause mesh
23 to lose strength in vivo?

24 A. It's my position that -- I

1 just believe I said that I would go back
2 to these articles.

3 I don't remember about the
4 strength. Didn't we just cover that?

5 Q. Okay. If the plaintiffs'
6 experts in this case take the position
7 that there is no loss of tensile
8 strength, would you defer to that?

9 A. I'm not claiming anything to
10 do with tensile strength that I can see
11 here.

12 What I said is, if it
13 degrades over time, it could lead to
14 embrittlement, cracking, and loss. And
15 those were things that were seen in the
16 complaint report.

17 So I'm bringing these back
18 that way. I am not a polymer scientist
19 that has analyzed the weight loss.
20 That's the wrong person.

21 Q. When you're discussing in
22 paragraph A complaints associated with
23 broken and torn mesh, are those
24 complaints that are prior to

1 implantation?

2 A. I would have to review those
3 specific complaints.

4 But there are complaints,
5 and also the Maude database right there.

6 Q. And so my question is: Are
7 you talking about complaints that mesh is
8 broken and torn prior to implantation?

9 A. No. That doesn't make any
10 sense. It's over time.

11 Q. All right. So --

12 A. If it came out of the box
13 that way, that's a manufacturing error.

14 Q. That's not what you're
15 talking about.

16 When you're talking about
17 broken and torn mesh, that's not what
18 you're talking about.

19 A. That is not my intent, no.

20 Q. And so if you have
21 referenced any complaints that --

22 A. Then there could be an
23 incorrect footnote. There could be a
24 typo on the footnote.

1 Q. Now, what is your support
2 for -- well, strike that.

3 Do you have the opinion that
4 vaginal erosion is caused by mesh
5 degradation?

6 MR. WALLACE: Are you asking
7 her as a clinician?

8 MR. COMBS: I'm asking her
9 as the person who wrote, Review of
10 the Maude database in 2008 risk
11 management legacy report also
12 revealed multiple cases of vaginal
13 erosion.

14 THE WITNESS: So if you look
15 at this report, they talk about
16 vaginal erosion.

17 They talk about the Maude
18 database. And there's -- oh, I
19 can hardly read this document.

20 And I think these documents
21 that say erosion -- let's see
22 here.

23 Repeat the question.

24 BY MR. COMBS:

1 Q. Here's what I'm asking.

2 Is it your opinion that the
3 degradation that you refer to on page 17
4 of your report, that that causes vaginal
5 erosion?

6 MR. WALLACE: That's outside
7 the scope of her report. And you
8 know it. And we're not offering
9 her as a clinician.

10 BY MR. COMBS:

11 Q. Okay. If you don't have
12 that opinion, that's fine.

13 MR. WALLACE: It's not
14 whether or not she has that
15 opinion. It's outside the scope
16 of her report.

17 MR. COMBS: Okay. I'll
18 accept that.

19 So, I mean it's in the
20 report --

21 MR. WALLACE: No, it's not.
22 She identifies harms and hazards.

23 And you're trying to ask her
24 clinical opinions right now, which

1 is, as you know, inappropriate.

2 MR. COMBS: If the
3 representation right now is --

4 MR. WALLACE: She's not
5 offering clinical opinions to you
6 as a physician. She is offering
7 you opinions as someone that's
8 involved in risk management.

9 I have had this very similar
10 discussion with someone on your
11 team, and think it was Byrd [ph]
12 at one point, and in another case.

13 But the bottom line is, just
14 so we're clear, we are not telling
15 you or Judge Goodwin that she is a
16 clinician.

17 She has identified documents
18 that support her opinion, and
19 she's identified harms and hazards
20 that were not recognized.

21 So if you are going to be
22 ask her medical opinions, there
23 are people that are offering those
24 medical opinions. You should go

1 talk to them.

2 BY MR. COMBS:

3 Q. Now, Ms. Wilson, is it
4 correct that you are not offering any
5 opinion in this case that degradation
6 causes vaginal erosion?

7 You are not offering that.

8 A. I am not a clinician. I
9 footnote that. I am not claiming
10 medical. I'm simply looking from the
11 complaints and from the hazard viewpoint.
12 I'm not an M.D.

13 Q. And you will not be opining
14 at trial that degradation in any way can
15 cause vaginal erosion.

16 A. What I can do is say that
17 the analysis of the data, just like I
18 have done from a risk management point of
19 view.

20 Q. Just --

21 MR. WALLACE: We're not
22 offering any medical opinions,
23 Phil.

24 THE WITNESS: No medical

1 opinion.

2 MR. COMBS: That will
3 include that she will not be
4 offering the opinion that
5 degradation causes a risk of
6 vaginal erosion.

7 If that's fair, then we can
8 move on.

9 MR. WALLACE: We're offering
10 no clinical opinions. We can move
11 on.

12 BY MR. COMBS:

13 Q. Ms. Wilson, you, on page 17,
14 discuss what you refer to as heavyweight
15 mesh.

16 A. On page 17?

17 Q. Yes. Page 17 you list --

18 A. Oh, D.

19 Q. What support do you have
20 that -- well, strike that.

21 Is the mesh in TVT
22 heavyweight?

23 A. I have read a doctor's
24 opinion and quoted the doctor. That's

1 the support I have.

2 Q. You don't know whether it's
3 heavyweight, do you?

4 A. I have read several of these
5 expert opinions from physicians. And
6 based on that, it is heavyweight.

7 Q. Do you know what the weight
8 is?

9 A. I believe it's -- I would
10 double-check. Based on these footnotes,
11 I think it was like between 110 and 120,
12 or -- it's all specified in there, and I
13 read those documents.

14 I don't have it memorized.
15 I understood this wasn't a memory test.

16 Q. And what is your basis to
17 conclude that the weight of TVT mesh
18 presents a risk that is not addressed in
19 the risk management processes of Ethicon?

20 A. So if you go back to the
21 original Preventia report, I don't think
22 it covered long-term effects like
23 inflammation.

24 Let's just look what it says

1 here.

2 In fact, I quoted scientific
3 literature right there, and medical
4 literature.

5 We looked at the complaints.
6 And as far as I know, there was no
7 evidence to say that that TVT-R had a
8 mesh change in it.

9 So the mesh itself wasn't
10 changed based on those complaint data and
11 the scientific evidence and the opinions
12 of the doctors.

13 So that's where I'm coming
14 from.

15 Q. Are you aware of any support
16 in the world that lighter-weight mesh in
17 an SUI application would cause less
18 clinical harms?

19 A. I believe the cited
20 footnotes clearly talk about that, yes.

21 Q. All right. And is --

22 A. That's not the whole world,
23 I'm sure. It's just the thousands of
24 pages I had available to me.

1 Q. Sure. And the article that
2 you're referencing is Dr. Klinge's
3 article about Foreign Body Reaction to
4 Meshes Used for the Repair of Abdominal
5 Wall Hernias.

6 A. I think there were
7 additional cites here, because there was
8 also this doctor -- I want to make sure
9 she's a doctor.

10 There's an article here
11 which is -- 10- -- not an article, excuse
12 me -- Footnote 109, Brigitte Hellhammer,
13 that says, yes, it is heavyweight, and
14 the mesh has been the same all the time.

15 So that's another reference
16 I have to say the mesh is heavyweight and
17 it hasn't been changed, coupled with the
18 other things that say, yes heavyweight
19 does have a more inflammatory response.
20 And then you have complaints.

21 So that circle has not been
22 completed, in my opinion; that you go
23 back look at those risks based on
24 feedback, then you make a change to the

1 product or do something to decrease or
2 mitigate.

3 Q. You do not have the medical
4 expertise to draw a causal relationship
5 between the weight of the mesh and
6 clinical outcomes, do you?

7 A. Absolutely not. But I
8 can -- here's what I can do.

9 Look at complaints and say,
10 has the risk management and quality
11 system process, have those been followed
12 that say, you need to go back and
13 evaluate those and do something about it?

14 And that's what I was trying
15 to say.

16 Q. And you would agree with me
17 that the weight of the mesh for all risk
18 analyses that has been done since 1997
19 would be for the same weight mesh?

20 A. I have no basis to state
21 that. I haven't looked at all risk
22 analyses.

23 MR. WALLACE: Off the
24 record.

1

- - -

2

(Whereupon, a discussion was

3

held off the record.)

4

- - -

5

BY MR. COMBS:

6

Q. Ms. Wilson, one of the risks

7

that you discuss is inability to remove

8

the mesh.

9

Is this intended to be a

10

permanent implant?

11

A. Yeah. It is a permanent

12

implant.

13

Q. And is there any question in

14

your mind that the surgeons that

15

implanted noted that it's a permanent

16

implant?

17

A. No. That's -- however, I

18

have worked on many permanent implants.

19

And I believe, as I have said, there are

20

a number of -- and right here, there are

21

a number of reasons a permanent implant

22

may need to be removed.

23

Q. Is the function of a mesh to

24

have tissue ingrow into it?

1 A. I'm not sure I can make a
2 clinical judgment about exactly how it
3 functions, but I do know it's intended to
4 be a permanent implant.

5 Q. And that surgeons who
6 implant it know that.

7 A. They certainly should.

8 Q. Ms. Wilson, I want to ask
9 you about your references to particle
10 loss on page 19.

11 A. Okay.

12 Q. Have you reviewed any of the
13 preclinical literature from Ethicon --
14 strike that.

15 Have you reviewed any of the
16 preclinical testing by Ethicon in which
17 they studied the risks associated with
18 particle loss?

19 A. I'm trying to remember. Was
20 it on my list?

21 I remember --

22 Q. I don't believe so.

23 A. I don't remember looking at
24 it.

1 Q. Do you know whether
2 Ethicon's preclinical department assessed
3 the risk of particle loss --

4 A. I don't know what their --

5 Q. -- from --

6 A. -- preclinical department
7 did.

8 Q. And have you reviewed the --
9 strike that.

10 Have you reviewed the
11 compilation of preclinical testing that
12 was introduced by Ethicon's 30(b)6
13 witness, Dr. Barbolt, regarding the
14 testing on degradation and particle loss
15 that was conducted by the preclinical
16 department?

17 A. No. That does not sound
18 familiar.

19 Q. You don't know what that
20 preclinical work showed, do you?

21 A. No. I don't think he's on
22 my list either.

23 MR. COMBS: Ms. Wilson, I'm
24 going to stop, and Mr. Wallace has

1 some questions for you.

2 There are a few items from
3 the file that you brought that
4 we're going to mark as exhibits.

5 So if we could just mark
6 those.

7 MR. WALLACE: Can we just
8 agree to do that after?

9 MR. COMBS: Yes, absolutely.

10 MR. WALLACE: That way, we
11 can move smoothly from here.

12 MR. COMBS: Sure. Thank
13 you.

14 - - -

15 (Whereupon, a brief recess
16 was taken from 5:55 p.m. to 6:00
17 p.m.)

18 - - -

19 BY MR. COMBS:

20 Q. Ms. Wilson, we pulled out
21 several documents from your file that we
22 are going to make a photocopy of and
23 attach them.

24 We're going to do that after

1 the deposition is over, but I just have
2 one question on one of them.

3 The document that says, GMS
4 Standard --

5 A. Q.

6 Q. I'm sorry.

7 -- QMS Standards and
8 Guidance, that's the document that you
9 were referring as your cheat sheet of the
10 standards?

11 A. Right. That's just a
12 summary we put together.

13 Q. Okay. And so this is a
14 summary you put together of the standards
15 that you --

16 A. Tried to keep it straight in
17 my mind.

18 Q. Okay. Thank you.

19 MR. DAVIS: And there's the
20 other one.

21 MR. COMBS: Okay.

22 - - -

23 EXAMINATION

24 - - -

1 BY MR. WALLACE:

2 Q. We're still on the record,
3 Ms. Wilson, and I'm going to just ask you
4 a few questions, and, actually, more than
5 a few.

6 How about that?

7 A. Sure.

8 Q. But I promise not to take
9 too long, because I know it's been a long
10 day for you.

11 So let me start sort of at
12 the beginning of the day.

13 You were asked about some
14 publications that you may or may not have
15 authored.

16 Do you recall that,
17 generally speaking?

18 A. Sure.

19 Q. And --

20 A. I'm trying to remember back.

21 Q. Let me ask you this. Well,
22 you mentioned one publication, if I
23 recall correctly, that was peer-reviewed.

24 In your field doing what you

1 do with medical device companies, what do
2 you believe is more important, your
3 publications or your work and experience?

4 A. In my field, very few
5 people -- you know, we don't publish
6 much. We do presentations, because we go
7 to seminars and give presentations.
8 Things like that are much more effective.

9 Q. You referred to, also
10 earlier in the day, your experience with
11 what you called implantables.

12 And if I'm right, you were
13 referring to permanently implantable
14 medical devices; is that right?

15 A. Correct.

16 Q. Why don't you tell us a
17 little about your experience with the
18 implantables --

19 A. Sure.

20 Q. -- over the course of your
21 30-year career?

22 A. I started working with them
23 about 1993. So before the -- those I
24 worked for Class I and II, and then I

1 started out with -- I worked with heart
2 valves, I worked with AAP, which are
3 ascending aortic prostheses.

4 I worked with tissue valves.
5 I've worked with, you know, a variety of
6 cardiovascular type of systems.

7 And then I moved on to a lot
8 of what I call total joints, which are
9 hip, knees, shoulders. And -- basically,
10 body parts. So I worked with lot of
11 those.

12 I also did a couple of
13 shoulder anchors. So those are also
14 intended to be permanently implanted.

15 Many of these are PEEK
16 devices, some are cobalt and chromium
17 devices. Some have different kinds of
18 polyethylene material in there.

19 So then I did quite a few
20 different spine.

21 And when I say I worked on
22 them, I not just worked on them, but I
23 mean I worked on maybe six versions of
24 them, yeah, because there were six

1 versions of them.

2 And then I worked with like
3 with interbody fusion devices, cervical
4 plates, medical screws. Those kind of
5 things.

6 Q. When you list all those
7 devices, if you can go a little bit
8 slower so we can take those down.

9 A. Sorry.

10 Q. Were some of those -- I take
11 it that some of those devices, like some
12 of those shoulders and knees, were made
13 of certain polymers or sometimes
14 plastics?

15 A. There were some components
16 of those that were polymers.

17 For example, in a knee,
18 there's often a polymer part between two
19 cobalt-chromium parts, and the shoulder
20 might have the same thing.

21 Q. Do you know whether or not
22 polypropylene is also a polymer?

23 A. Yes, it is.

24 Q. And is it fair the say that

1 you're a biomedical engineer --

2 A. Yes.

3 Q. -- by training?

4 A. It's what my education is
5 in.

6 Q. If I recall correctly, you
7 said that you worked for a QA unit for a
8 mesh.

9 What do you mean by that?

10 A. Well, in -- if you have a
11 GLP study, so a preclinical animal study,
12 but first you have to get registered to
13 be certified.

14 And then -- anyway, this
15 facility did large animal studies, sheep,
16 pigs -- sheeps and pigs primarily.

17 And so a QA unit makes sure
18 the study is enacted properly. It
19 follows the rules of 21 CFR 58. Just a
20 different part of the FDA regulations
21 that deals with good laboratory
22 practices.

23 And so my job was to make
24 sure the studies were adhered to and that

1 the good laboratory practices were
2 performed.

3 Q. Switching topics. You were
4 asked earlier about the number of
5 meetings, calls, and/or conference calls
6 that you might have had.

7 You mentioned one call that
8 you had in connection with this report.

9 Were you referring to phone
10 calls or formal conference calls?

11 A. That was a formal three-way
12 call. I realized later that there were a
13 bunch of little cell phone calls, but I
14 was thinking of the formal conference
15 call.

16 Q. You were asked some
17 questions earlier about QSIT.

18 Do you recall that?

19 A. I saw that the QSIT guide
20 was out, yes.

21 Q. And you were asked some
22 questions about that earlier today?

23 A. Yes.

24 Q. And I wrote a note to

1 myself.

2 Are QSIT inspections
3 different than the work that is the
4 subject of your expert report?

5 A. Really, QSIT inspections
6 have no bearing on my report.

7 I mean QSIT inspections
8 are -- you know, that's how FDA was
9 trained ten years ago on doing
10 inspections.

11 Some people still follow it,
12 but that really has no bearing on risk
13 management, quality management systems in
14 medical devices.

15 Q. Thank you, Ms. Wilson.

16 Let's talk about that for a
17 few more minutes, because you've raised
18 it.

19 You were asked a lot of
20 questions earlier about the FDA and
21 regulators.

22 Are the FDA regulations
23 necessary to the analysis and opinions
24 that you offered in your expert report?

1 A. No.

2 Q. Why not?

3 A. Because the same type of
4 regulations are in the other standards
5 that I did cite. This specifically was
6 not to talk about the FDA.

7 This is about there's
8 guidance documents out there. There's
9 documents that have been out there for 30
10 years that aren't specific to the FDA
11 that govern how medical device
12 manufacturers should do these things.

13 Q. So, in other words, if you
14 were told that your report -- the subject
15 of your report and your testimony at
16 trial, that you cannot mention the FDA,
17 is it fair to say that you could offer
18 your opinions at trial without even
19 mentioning the word "FDA"?

20 MR. COMBS: Objection to
21 form.

22 THE WITNESS: Absolutely.

23 BY MR. WALLACE:

24 Q. Were you ever -- you gave

1 some -- at least you tried to give some
2 examples in an exchange with Mr. Combs
3 about what you have been involved in the
4 past for companies that had certificates
5 that were issued to them.

6 Do you remember that?

7 A. I do.

8 Q. And I'm specifically
9 referring to Exhibits 6 and 7, which
10 appear to be certificates relating to --
11 relating to Ethicon and in the EC.

12 Do you recall that?

13 A. I do.

14 Q. Have you ever worked on
15 product holds or recall involving medical
16 devices?

17 MR. COMBS: Objection to
18 form.

19 THE WITNESS: Yeah. One
20 year, in fact, I had 17 recalls I
21 had to deal with when I was a
22 young engineer.

23 I've also had, you know,
24 product holds. I think I was

1 telling about the infections where
2 all of a sudden we had like three
3 or four, and then within like a
4 couple-of-week period, so we
5 stopped everything, because we
6 weren't sure -- we just weren't
7 sure what the source was, so we
8 stopped everything and formed a
9 team.

10 We had, like, clinical
11 people. We had doctors,
12 pathologists, engineers, the
13 design engineers, QA people,
14 regulatory. And we just all
15 jumped in on it and tried to
16 figure out what was going on.

17 We asked for the products
18 back, because they had -- some had
19 to be explanted.

20 But, you know, there are
21 various degrees of infections out
22 there.

23 BY MR. WALLACE:

24 Q. You talked about a team.

1 Did I hear you correctly that you
2 assembled that within two weeks?

3 A. I can't tell you the exact,
4 it could have been a week, it could have
5 been two weeks.

6 I mean, as soon as we became
7 sure there was something going on, and
8 I'm -- basically, overnight, by the time
9 you decide to do something, you do
10 something.

11 Q. Are pathologists ever part
12 of a team like that, involving
13 permanently implantable medical devices?

14 A. In my experience, there's a
15 pathologist sort of that works with a
16 company to evaluate explants. So it's a
17 routine to get an explant.

18 And that's why I brought
19 up -- you know, even though they're
20 supposed to be permanently implantable
21 devices, things happen.

22 You have to have a knee
23 explanted, a heart valve, you know.

24 Unfortunately, you pretty much -- you can

1 replace a heart valve. It's not a very
2 good process, but -- and then you have
3 pathologists and other scientists that
4 evaluate the cause of the problem.

5 Q. And, in fact, have you been
6 part of teams that have been assembled to
7 do just that, that also have those kinds
8 of professionals on them.

9 A. Yeah, I mean --

10 MR. COMBS: Object to form.

11 THE WITNESS: Yeah. I've
12 part of times that basically
13 whoever the company believes is
14 needed.

15 You draw your group, you
16 draw your core team, and you draw
17 a leader.

18 BY MR. WALLACE:

19 Q. In your role as a consultant
20 after you left the industry, have you
21 ever been involved in recalls or product
22 holds?

23 A. Yes, I have, which is
24 interesting.

1 Q. Have some of those companies
2 been given certificates that their
3 systems are okay?

4 MR. COMBS: Objection.

5 THE WITNESS: Well, I mean
6 the certificate is the
7 certificate.

8 And some of the companies --
9 I could think of one in
10 particular, and I was trying to
11 explain, they were there on a rain
12 day, I mean an ice day. The
13 company wasn't even running. They
14 got their certificate.

15 And then I went in to do an
16 audit, and they were not even
17 keeping inspection data. So there
18 was no way for you to even know if
19 your device met specifications.

20 So, yeah, I mean the company
21 can be executing great or they can
22 be doing not so great, in my
23 experience.

24 BY MR. WALLACE:

1 Q. And you're -- well, we'll
2 get to that.

3 A. I just want to add. That's
4 why I said there was a big variation
5 between notified bodies.

6 Q. You were asked a lot about
7 the different dates for standards, and
8 you identified when some of those
9 standards went into effect.

10 My question is this. Do
11 companies know that these standards are
12 coming, so that they can transition to
13 them?

14 A. Absolutely.

15 MR. COMBS: Object to form.

16 THE WITNESS: There's -- for
17 example, I knew about design
18 controls years before we had
19 design control systems, as far
20 back as '93 established, just
21 ready for implementation in '97.

22 Most of these are coming
23 and, they give a two or three-year
24 window to even be compliant.

1 So there's all kinds of --
2 AdvaMed and all kinds groups that
3 tell you what's coming, what's
4 coming yesterday, what's coming
5 tomorrow.

6 BY MR. WALLACE:

7 Q. You were asked a fair amount
8 of questions about what surgeons might
9 have been trained on, what surgeons'
10 opinions were, and other issues regarding
11 medicine.

12 Do you have to be a doctor
13 to identify hazards as part of the risk
14 management process?

15 MR. COMBS: Object to form.

16 THE WITNESS: No. In fact,
17 generally, the doctors don't
18 understand the risk management
19 process. That's why people like
20 myself and others that have done
21 this for a long time are asked to
22 facilitate the process.

23 They don't know the
24 standards. They don't know the

1 processes. They don't know inputs
2 and outputs and what needs to be
3 considered.

4 They are knowledgeable
5 about -- know how to place it and
6 how to, you know, do informed
7 consent.

8 BY MR. WALLACE:

9 Q. You used the word "input" in
10 connection with Exhibit 9, which is the
11 position statement on mesh that you were
12 shown. And I think you referred to it as
13 a white paper.

14 Do you recall that?

15 A. Oh, yeah. Yes.

16 Q. And you said -- and I think
17 you were cut off, so I want to make sure
18 that we address this.

19 You said that you need to
20 get other inputs and other positions from
21 other people.

22 And I'm sort of paraphrasing
23 your testimony, because I don't believe
24 it was complete.

1 Is what you are saying, when
2 you're designing and understanding the
3 risk processes, that you actually, as a
4 medical device company, a reasonable one,
5 would actually seek out position papers
6 or information from those who might
7 oppose your views?

8 MR. COMBS: Object to form.

9 THE WITNESS: I think I --
10 when I went back and I said that
11 there's lots of inputs. And you
12 would get inputs from all types of
13 sources.

14 And I'd have a picture in
15 there, too, of the various inputs
16 you would get.

17 So, yeah, you would look at
18 ones that support your opinions,
19 ones that wouldn't support your
20 opinions.

21 You would look at clinicals,
22 you would look at complaints. You
23 would look at -- it's in one of my
24 figures -- all kinds of sources of

1 input.

2 BY MR. WALLACE:

3 Q. And, in fact, you were asked
4 yourself, the word "reliance" was used or
5 documents considered.

6 Is it fair to say that you
7 looked at all the documents that were
8 given to you and carefully considered,
9 even those that may not entirely support
10 your views?

11 MR. COMBS: Object to form.

12 THE WITNESS: I looked at a
13 lot of documents, and looked at --
14 I tried to be fair and look at
15 those all objectively, whether
16 they supported or didn't support
17 my views.

18 I'm sure that there were
19 some I spent more time on than
20 others.

21 BY MR. WALLACE:

22 Q. Let's move on to a topic
23 that we approached towards the middle to
24 late afternoon.

1 And it's this idea in
2 Exhibit 13, in the risk analysis that was
3 done in 2001.

4 I'm sure you remember,
5 generally, that line of questioning, but
6 I'm putting the document in front of you
7 to refresh your recollection.

8 Do you recall seeing that
9 earlier today?

10 A. Yes, I do.

11 Q. You were asked
12 some questions -- or it was represented
13 to you by Mr. Combs that that document
14 was not on your reliance list. And you
15 seemed to take great exception to that.

16 You saw this a long time
17 ago?

18 A. I mean, I looked at the
19 whole 1,000-page file. And I'm sure I
20 looked at this, because I remembered --
21 because I'd never seen before something
22 that just said, Non-imaginable.

23 That was my memory jogger.
24 And I looked at it, and I just looked,

1 oh, my gosh, that's incomplete.

2 It doesn't even fill in half
3 the things. So that's how I distinctly
4 remember I looked at it.

5 Q. And this Exhibit 13, you're
6 specifically talking about Exhibit 13.

7 A. Yes.

8 Q. So you had seen it before
9 you finalized your report; correct?

10 A. Yeah, I did.

11 Q. And it became one of the
12 documents that you considered in reaching
13 your opinions.

14 A. That's why I went on to say
15 that I didn't think things were done
16 adequately, because, in my opinion,
17 that's very inadequate. It doesn't even
18 talk about a lot of the severities.

19 I mean, if you look at this
20 report, it starts out giving some things,
21 you know. But the risk classes are all
22 1s, 0s. Things are missing. It's
23 incomplete.

24 A whole page, it just says,

1 No hazard, No hazard, Not imaginable.

2 That's not a respectful job,
3 in my opinion.

4 Q. Mr. Combs led you through a
5 number of questions on Exhibit 13 and
6 compared what was listed in Exhibit 17 to
7 that.

8 Do you recall?

9 A. I do.

10 Q. And more specifically, just
11 so it's clear for the record, we're
12 talking about an Exhibit 17, the
13 April 25, 2002 memorandum that is
14 entitled "Device Design, Safety
15 Assessment Re-evaluation for TVT"; right?

16 A. Right.

17 Q. And if I understand --
18 because this line of questioning was
19 quite extensive.

20 If I understand you
21 correctly, is it your opinion that you
22 have expressed in your report that the
23 right hand doesn't know what the left
24 hand is doing when it's coming to risk

1 management?

2 MR. COMBS: Object to form.

3 THE WITNESS: It's my
4 opinion, yes, that there's bits
5 and pieces, but it's not a
6 cohesive risk management system.

7 So 2002, per this document,
8 they're saying these are new, and
9 these are the complaints.

10 BY MR. WALLACE:

11 Q. But, in fact, some of them
12 were not new?

13 A. Some of them had been
14 addressed in this report that I didn't
15 feel was adequate. It just didn't
16 even -- and those that we looked just
17 were blank. They weren't assessed. They
18 weren't listed.

19 Q. So, in fact, that someone at
20 Ethicon is calling complaints new
21 actually support your opinion?

22 MR. COMBS: Object to the
23 form.

24 THE WITNESS: You know, it's

1 just showing that there's not a
2 cohesive quality and risk
3 management system.

4 BY MR. WALLACE:

5 Q. I believe it was represented
6 to you that -- and I could be wrong,
7 we'll let the record be whatever it is --
8 that all of the hazards were identified,
9 but -- and you can take your -- let me
10 make this clear for the record.

11 A. Okay.

12 Q. I believe that it was
13 represented to you that all of the 11
14 hazards identified in Exhibit 17 were
15 prior -- were identified in Exhibit 13,
16 which is the prior what we'll call risk
17 analysis.

18 Do you recall that line of
19 questioning?

20 A. Yes, I do.

21 Q. I'm going to let you look
22 through here, but there is no reference,
23 is there, to dull needles, mesh kink,
24 torn mesh, mesh broken, are there?

1 MR. COMBS: Can you repeat
2 that question.

3 - - -

4 (Whereupon, the requested
5 portion was read.)

6 - - -

7 BY MR. WALLACE:

8 Q. Or mesh twisted?

9 A. I do see, and just to be
10 fair, that it says, The tip is not as
11 sharp.

12 Q. Fair enough.

13 A. So it's similar to dull.

14 And now I'm looking for the
15 torn mesh.

16 Torn mesh and what was the
17 or one?

18 Q. Mesh kinked, twisted.

19 A. I'm going through carefully.
20 I don't see anything about twisted or
21 kinked mesh.

22 Q. So if, in fact, a clinical
23 expert testifies that the TVT ropes and
24 curls, that was clearly not referenced in

1 Exhibit 13; right?

2 MR. COMBS: Object to the
3 form.

4 THE WITNESS: I don't see it
5 listed in the hazards.

6 BY MR. WALLACE:

7 Q. And, in fact, you identified
8 in your report five critical hazards that
9 were never addressed --

10 A. Where is the report?

11 Q. -- through the risk
12 management process; right?

13 A. Right. I just have to find
14 my report again.

15 Right there.

16 Q. That's fine.

17 While you're getting the
18 report, let me ask you something for
19 clarification so that it's -- so that
20 we're all singing from the same hemline,
21 so to speak.

22 The fact that someone may
23 send an email or a document is prepared
24 somewhere that mentions the word, say,

1 "degradation" or mentions the word
2 "particle loss," that, in fact, may
3 exist; right?

4 There might be a document
5 out there in all of the documents that
6 you reviewed that uses the word
7 "degradation" or uses the word "particle
8 loss"; right?

9 A. Right. I mean, that's
10 why --

11 MR. COMBS: Object to form.

12 THE WITNESS: -- I kept
13 saying if I missed something,
14 please show me.

15 BY MR. WALLACE:

16 Q. But at the end of the day,
17 have you seen anything in either this
18 2001 document, which is Exhibit 13, and
19 Exhibit 17, or any of the risk documents
20 that you reviewed that appropriately
21 addresses the risk management process at
22 Ethicon --

23 MR. COMBS: Object to form.

24 THE WITNESS: No.

1 BY MR. WALLACE:

2 Q. -- when it comes to the five
3 critical hazards that you identified?

4 A. No. What I haven't seen is
5 that the feedback system is functional
6 and it goes back and is addressed.

7 And I address that in my
8 report specifically.

9 Q. So, in other words, the
10 opinions that you have expressed that
11 these five hazards -- you still hold that
12 same opinion today?

13 A. Right.

14 MR. COMBS: Object to form.

15 BY MR. WALLACE:

16 Q. Even after all the questions
17 by Mr. Combs; correct?

18 A. Right.

19 Q. Now, you said earlier that
20 Exhibit 13 had a different Bates number,
21 and there was an exchange about that.

22 A. Right.

23 Q. You're basing that off your
24 memory; correct?

1 A. Yes, I am.

2 Q. So, in fact, whether or not
3 it has a different Bates number, you
4 remember reviewing Exhibit 13 and
5 considering it and addressing these
6 issues in your report.

7 A. I do.

8 Q. You represented that the
9 documents were electronically provided to
10 you. You're not sure whether or not they
11 exist.

12 Is it, in fact, the case
13 that some hard copies were also shared
14 with you at some point?

15 A. Yes. There were two binders
16 of hard copies.

17 I didn't go back and look at
18 those, because I had already set up a
19 system. But I do have two binders of
20 hard copies.

21 Q. There was an exchange
22 between you and Mr. Combs earlier where
23 you indicated that some risks were
24 identified in Exhibit 13, which is the

1 2001, what we'll call a risk assessment.

2 Why did you qualify your
3 answer with some risk?

4 What is your criticism in
5 that regard?

6 A. I think that document is
7 just inadequate. It is not good. It
8 does not follow the intent of risk -- of
9 a risk management -- of a design risk
10 analysis.

11 And I say that based on the
12 fact that it's incomplete.

13 I know people have reviewed
14 it. But to just say it's not imaginable,
15 to not fill in probabilities, and then at
16 the end of the day everything was
17 acceptable.

18 Q. And is that the basis in
19 which you prepared your report?

20 A. Right. And then I called
21 out in the other ones where, you know,
22 all of a sudden, well, it's acceptable.
23 We just have an IFU and it's all
24 acceptable.

1 I mean, I'm generalizing
2 there, but it does say, general risks for
3 the procedure, acceptable, acceptable,
4 acceptable. And then there's a bunch of
5 blanks, a whole page of blanks,
6 negligible, more blanks. So...

7 Q. You were shown a number of
8 laser cut documents, and documents
9 relating to the TVT-Exact and the TVT-O.

10 If I can just try to cut
11 through a lot of time on this issue.

12 Is it fair to say that you
13 did not rely on those risk profiles to
14 examine the risk management process for
15 the TVT because it's your opinion that
16 each product or iteration of a product
17 needs to be examined separately, and you
18 felt that that was the case when it came
19 to the TVT and the other products that
20 were examined?

21 A. Right. Yes.

22 Q. You were asked a lot of
23 questions about audits. And I believe
24 you were shown some audit reports.

1 Is there a difference
2 between an audit and the reports that you
3 regularly prepare for device companies
4 that address risk management?

5 A. Could you repeat that
6 question? I'm sorry.

7 Q. Yes.

8 Well, what I'm getting at is
9 there's a difference between an audit and
10 a -- for example, a consulting report
11 where you might be asked to go into a
12 medical device company to look at the
13 risk management process.

14 A. Oh, yeah. It's exactly what
15 I described earlier.

16 An audit is a specific set
17 of -- a point in time to a specific
18 standard. And, generally, like my audit
19 reports are about 40 pages long with
20 specific things that are
21 non-conformances, a checklist and very
22 detailed to that standard, with examples.

23 Q. So just to be clear, you
24 have actually walked in the doors of

1 medical device companies over the course
2 of your career and performed the same
3 analyses that you performed here, right,
4 by looking at their risk management
5 processes and identifying strengths
6 and/or weaknesses?

7 A. Right. Those would be
8 called -- like we call them gap analyses.
9 They're not audits. So we would go in
10 and do a gap analysis to look, gee, how
11 did they, you know, comply with the
12 standards? How did they respond over
13 time? How do their documents, you know,
14 look?

15 And then we provide them a
16 management report.

17 Q. And when you did your expert
18 report in this case, did you use the same
19 methodologies that you use in your
20 professional consulting for medical?

21 A. Yeah. It's similar.

22 And then I look -- I
23 consider my background and experience. I
24 looked at -- as an auditor, I looked at

1 my consulting. And then I use all of
2 those skills together to come up with a
3 report, looking at the gaps and the
4 opportunities for improvements.

5 Q. You're familiar with the
6 concept of under-reporting of complaints;
7 correct?

8 A. Yes.

9 Q. And is it your experience
10 that the medical device industry is
11 supposed to assume that there is
12 significant under-reporting of
13 complaints; right?

14 A. I mean, it's known that -- I
15 don't know that you can quantify how much
16 is underreported, but I do know that
17 there is not only under-reporting of
18 complaints, but there's under-reporting
19 of MDRs. It's a lot up to the specific
20 management and the specific -- actually,
21 even the user facility, staff to the
22 hospital.

23 Q. You used the word -- and I
24 could be wrong about this, so please

1 correct me if I'm wrong.

2 When you were asked about
3 particle loss earlier, you said you
4 reviewed some documents relating to blue
5 particulates.

6 Do you recall that?

7 A. Yeah.

8 Q. And what do you recall
9 reviewing?

10 A. I'm trying to remember.

11 Q. And if you do recall, what
12 was significant to you about it?

13 A. Well, I think there were
14 differences of opinion even within the
15 documents I reviewed.

16 But I remember some people
17 said you can see them better, so they're
18 good, and other people said, well,
19 particulates are bad because you can
20 cause pain.

21 Some said they are
22 biocompatible, so it doesn't matter.
23 Other people said, but in the vagina they
24 move and they can cause other problems.

1 So I think there's a
2 difference of opinion regarding -- I
3 mean, this is what I member about those
4 particles.

5 Q. Fair enough.

6 So even in Ethicon, if there
7 is a difference of opinion on the
8 clinical significance of the particle
9 loss, is it your opinion that Ethicon's
10 risk management should have addressed
11 that regardless of the difference of
12 opinion?

13 A. Yeah. I think together with
14 their quality system, which reviews
15 things periodically, and then they pull
16 in the risk management system when
17 appropriate.

18 So that goes back to the
19 complaints and the follow-up and all
20 those sources of input. And then you're
21 supposed to review those and update your
22 risk management when things change or
23 when you see difference in technology and
24 things like that.

1 And that's in those
2 standards.

3 Q. You were criticized -- you
4 know, you've read Ms. Duncan's report;
5 correct?

6 A. I did, but I don't have it
7 memorized.

8 Q. Fair enough.

9 Well, there was also some
10 testimony on this topic today as well, so
11 I'm going to go ahead and ask the
12 question.

13 You talked about in the
14 quality management system and risk
15 process that a company has to mitigate,
16 and as part of that, they may have to
17 change their design.

18 You were criticized by
19 Ms. Duncan for suggesting that, and there
20 was also some testimony on that issue
21 today.

22 I want to get something -- I
23 want to understand this better from you.

24 You're not suggesting, are

1 you, that every time there's an issue,
2 that there needs to be a redesign, are
3 you?

4 A. No. What I'm trying to say
5 is that you need to re-evaluate, and
6 there may need to be -- if the risk is
7 too high, you may need to redesign it, or
8 you may implement a change to a new
9 product and discontinue another project
10 line.

11 You know, if you come up
12 with a new product, why would you keep
13 the old TVT out there? Or you might come
14 up with some other mitigations, which I
15 have a picture of, like new accessories,
16 or more -- you know, tighten down the
17 manufacturing process so there's less
18 variability.

19 There's a number of ways
20 that you can get to the same thing.

21 Q. So, in other words, you
22 would fit the solution to address the
23 problem.

24 A. Absolutely.

1 Q. Okay. You were shown some
2 documents with respect to some surgeon
3 training, and you were asked about that
4 in connection with some of the risk
5 documents.

6 Assuming that, in fact,
7 Ethicon engaged in some training, does
8 that in and of itself solve the entire
9 problem and change the opinions that
10 you've expressed in your report?

11 A. Well, okay. Let's assume
12 that they did the training, which they
13 probably did.

14 To me, that just means that
15 the training must not have been fully
16 effective if they did it in 2000 and
17 they're still having the same
18 complaints -- more complaints in 2002,
19 and then there was more complaints in
20 2006.

21 So it's that same cycle that
22 I keep trying to go back to, that the
23 process must not have been effective
24 throughout.

1 Q. And is one of the failures
2 to be effective, could that be the
3 internal people that are not adequately
4 addressing the feedback that's coming
5 back from the field?

6 A. Yeah, I really don't know
7 the reason, but that certainly could be
8 one of them.

9 MR. WALLACE: Give me one
10 minute.

11 Nothing further.

12 MR. COMBS: I'll keep it
13 really brief.

14 - - -

15 FURTHER EXAMINATION

16 - - -

17 BY MR. COMBS:

18 Q. Ms. Wilson, you testified to
19 some questions that Mr. Wallace asked you
20 about a product that had an infection
21 problem. I just want to make sure that
22 the record is clear.

23 That doesn't have anything
24 to do with TVT, does it?

1 A. No. That was an example in
2 my consulting career.

3 Q. Now, Mr. Wallace asked you
4 about the need to take consideration of
5 opposing views.

6 Do you remember those
7 questions?

8 A. I do.

9 Q. Do you know what reviews
10 Ethicon does of the clinical literature
11 regarding this product?

12 A. I didn't look at the
13 clinical evaluation reports. And I don't
14 think that was cited in my --

15 Q. So the answer is you don't
16 know.

17 A. No.

18 Q. You made a comment about
19 under-reporting of complaints and MDRs.

20 You don't have any
21 information that Ethicon has
22 under-reported any complaints or MDRs, do
23 you, about TVT?

24 A. I was talking about the

1 industry in general, not your -- not
2 Ethicon specifically.

3 Q. Now, are you aware that
4 Ethicon tracks complaints by specific
5 product code?

6 A. I do know that you have a
7 database -- Ethicon has a database and
8 they track it to product code. I think I
9 saw that.

10 Q. And so, for example,
11 complaints regarding TVT mechanically cut
12 are tracked by that product code, aren't
13 they?

14 A. I would assume so. I didn't
15 go analyze, but usually they're to the
16 ref number, which is like the catalog
17 number. That's generally how
18 manufacturers do it.

19 Q. And there is a different I
20 call it SKU number, but there's a
21 different SKU number for TVT mechanically
22 cut and TVT laser cut, isn't there?

23 A. I would have to just your
24 judgment on that.

1 Sometimes people do that,
2 and sometimes they don't. Depending if
3 they think it has similar form fit or
4 function, they decide to keep the same
5 ref number. And I just couldn't tell you
6 how far that got carried through at
7 Ethicon.

8 Q. But your understanding,
9 complaints are tracked by product code.

10 A. I believe I saw that.

11 Q. You said that there was no
12 reference to torn or broken mesh in the
13 risk analysis?

14 A. I just was looking back
15 through Exhibit --

16 Q. Thirteen.

17 A. -- 13, and I didn't see it.

18 Q. But, in fact, there were
19 hazards assessed regarding strength of
20 mesh, weren't there?

21 A. Well, strength is not the
22 same as -- to me. That wasn't what I was
23 asked.

24 Q. Okay.

1 A. I can go look for that if
2 you would like me to.

3 Do you want me to go look at
4 that right now?

5 Q. Sure.

6 A. It talks about tensile
7 strength, which, to me, is different than
8 the complaints I saw.

9 Q. And so tensile strength of
10 the mesh was one of the things in the
11 risk analysis.

12 A. Right.

13 Q. And you've never -- strike
14 that.

15 One of the questions
16 Mr. Wallace asked you was about the risk
17 of twisting the mesh.

18 And I want to make sure I
19 understood your answer.

20 You're not equating the
21 twisting of the mesh that is referenced
22 in the 2002 memorandum, you're not
23 equating that as being the same thing as
24 roping and curling, are you?

1 MR. WALLACE: Objection to
2 form.

3 THE WITNESS: In my report,
4 I think I call it -- I would have
5 to go back and look. There's
6 twisting. There's roping and
7 curling. There's different types.

8 One is when it doesn't lay
9 flat when it's implanted. That's
10 what I think is twisting. And I
11 cited that in my report.

12 I didn't see twisting on
13 here.

14 BY MR. COMBS:

15 Q. Okay. So you're equating
16 roping and curling with a twisting of the
17 mesh.

18 A. I would have to look at my
19 report. I think that there are
20 different --

21 MR. WALLACE: It's right
22 here.

23 THE WITNESS: I think I was
24 asked if those are on this report,

1 which is Exhibit 13.

2 Is that what you were -- no.

3 I forgot your question altogether
4 now.

5 BY MR. COMBS:

6 Q. My question is on -- I
7 thought I heard you testify that mesh
8 twisting, as referenced in the 2002
9 memorandum that we talked about, that
10 that is the same thing as roping and
11 curling.

12 So if I misunderstood that,
13 that's fine. I just want to see if that
14 is or is not your understanding.

15 A. I don't believe that's what
16 I was asked.

17 I was asked if the mesh
18 roping/curling or TVT mesh fraying were
19 my five -- some of these were on here, is
20 what I thought I was asked.

21 Q. Okay. So you do not equate
22 mesh twisting as being the same thing as
23 roping and curling.

24 MR. WALLACE: Objection to

1 form. Asked and answered.

2 THE WITNESS: If I look at
3 my report, B, it says, Roping,
4 curling, deforming. C is fraying
5 and particle loss.

6 BY MR. COMBS:

7 Q. Ms. Wilson, what's your
8 basis for believing that torn or broken
9 mesh referred to is referring to
10 postimplantation?

11 A. Torn or broken mesh?

12 Q. Yes, ma'am.

13 A. It makes no sense. If it
14 comes out of the box torn or broken, then
15 that's a manufacturing defect. It's not
16 something to do with degradation over
17 time.

18 It's a definition of over
19 time versus at a point in time. A
20 manufacturing defect is out of the box
21 failure, we call it.

22 Q. Okay. And so if the
23 complaints are talking about torn or
24 broken mesh preimplantation --

1 A. Then there must have been a
2 wrong footnote. I think we went through
3 that, because that wasn't the intent.

4 Q. And you talked about your
5 criticism of the risk analysis making a
6 finding that the risks were acceptable,
7 the 2001 risk analysis.

8 Do you remember that?

9 A. Yes, I do.

10 Q. Now, are you aware of the
11 clinical expert reports that have been
12 prepared by physicians at Ethicon that
13 have weighed the benefits versus the
14 risks of these products?

15 A. I think I established that I
16 looked at a couple clinical expert
17 reports, certainly only a couple, and I
18 said I'm sure that they're in my body of
19 evidence.

20 So that's all I can say I'm
21 aware of.

22 Q. And there were clinical
23 expert reports in 2000, 2001, 2006, 2010,
24 and 2013, that all assess that exact

1 issue of whether the risks outweigh the
2 benefits of the product.

3 A. That's not what I was
4 talking about.

5 I was talking about in that
6 assessment -- I wasn't looking at the
7 clinical harm risk/benefit decision. I
8 was looking -- and I even cited like 93
9 percent of those, the engineering said --
10 let's just go right to it in my report.

11 That's not at all what I was
12 saying. I'm sorry. It's getting dark in
13 here.

14 Q. The good news is we're about
15 two minutes from being done.

16 A. So what I was saying, on
17 page 12 of my report said that, The
18 review of the aFMEA from 2000 Issue 8
19 showed that the probability of occurrence
20 of failure in 41 of 44, meaning 93
21 percent of potential failure modes,
22 showed either no risk identified, not
23 likely, or very low.

24 So I'm not looking at the

1 clinical list. I'm specifically looking
2 at the probability of occurrence of those
3 failures. So that's an engineering
4 judgment, I believe, that was made at the
5 time they did the aFMEA, or a team
6 judgment.

7 Q. Okay. And my only question
8 is: Are you aware of the fact that there
9 have been clinical expert reports, at
10 least five of them, that have assessed
11 the risks versus the benefits of the
12 product, and concluded that the benefits
13 outweighed the risks?

14 A. Same answer. I have only
15 looked at a couple. And if I put them in
16 the report I have seen them, otherwise,
17 I'm not aware of them.

18 MR. COMBS: Thank you. I
19 have no further questions.

20 MR. WALLACE: I just have
21 one, just because you used it in
22 your answer.

23 - - -

24 FURTHER EXAMINATION

1

- - -

2 BY MR. WALLACE:

3 Q. You referenced 1,000 pages.

4 And because of this issue of what

5 clinical expert reports you may or may

6 not have looked at, you mentioned 1,000

7 pages earlier, and were referencing, I

8 believe, Exhibit 13.

9 Is it true that you have

10 looked at documents in connection with

11 the risks that were assessed at this

12 point in time?

13 A. Right. And in that

14 technical file, there were a whole bunch

15 of process validations. There were

16 prints. There were a variety of things

17 like that.

18 There were, you know,

19 sealing studies, there were peeling

20 studies. There may have been a clinical

21 evidence report that I missed.

22 But what I looked, it looked

23 like a traditional technical file that

24 had all of the process validation, the

1 specs, the -- those kind of things.

2 Q. And you did review that
3 file; correct?

4 A. Yes, I did. And the risk
5 documents were in that file.

6 Q. And you keep pointing to
7 Exhibit 13, so the risk --

8 A. Well, the Preventia was in
9 there. That was -- Exhibit 13 was in
10 there. The Preventia ones were in there.
11 They were in there.

12 MR. WALLACE: Nothing
13 further.

14 MR. COMBS: Nothing more
15 from me.

16 - - -

17 (Whereupon, Exhibits 20
18 through 28 were marked for
19 identification.)

20 - - -

21 (Whereupon, the deposition
22 concluded at 6:49 p.m.)

23 - - -

24

C E R T I F I C A T E

I HEREBY CERTIFY that the
witness was duly sworn by me and that the
deposition is a true record of the
testimony given by the witness.

— — — — —
Margaret Peoples, RPR
Dated: September 17, 2015

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1 ACKNOWLEDGMENT OF DEPONENT

2
3 I, _____, do
4 hereby certify that I have read the
5 foregoing pages, _____ and that the
6 same is a correct transcription of the
7 answers given by me to the questions
8 therein propounded, except for the
9 corrections or changes in form or
10 substance, if any, noted in the attached
11 Errata Sheet.

12 _____
13 ANNE HOLLAND WILSON, MBA DATE

14
15 Subscribed and sworn to before me this
16 _____ day of _____,
17 20____.

18 My commission expires: _____
19
20 _____
21

22 Notary Public
23
24